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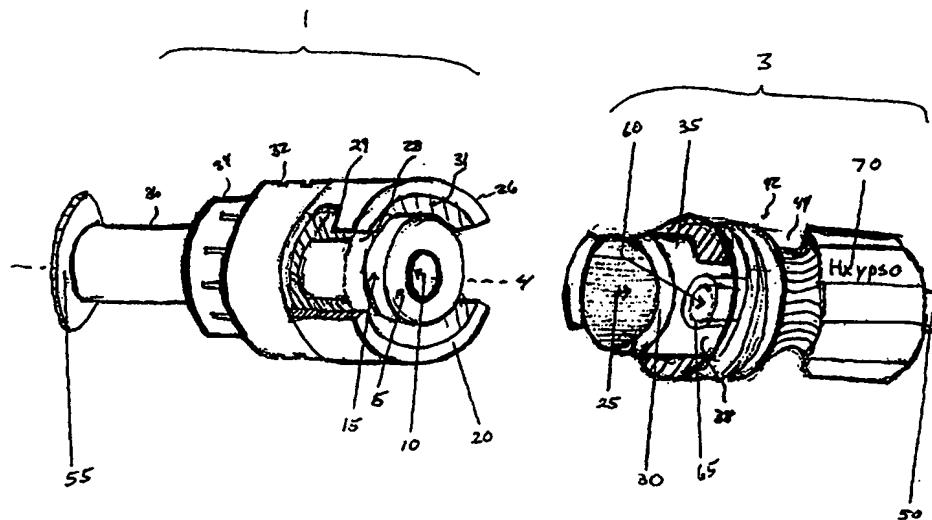
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(54) Title: SAFETY INDEXED MEDICAL CONNECTORS



(57) Abstract

A medical connector adapted for placement between a catheter and a medical infusion or injection source includes a pair of interlocking half medical connector portions, one side of which attaches to the infusion source and the other side of which is coupled to the catheter connected to the patient. The connection to the catheter and the infusion source can be via standard medical luer taper fittings, with or without specially designed locking mechanisms that prevent inadvertent disconnection. The medical connector itself is uniquely shaped and includes a raised surface feature and a recessed surface feature formed on the medical connector portions.

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SAFETY INDEXED MEDICAL CONNECTORS

Background of the Invention

The present invention relates to fluid connectors, and more particularly to fluid connectors used in medical environments and designed to ensure the correct and appropriate administration of medicaments to a patient.

Errors in prescribing and delivering medications to patients are, unfortunately, common in medical practice. Many of these mistakes result in patient injury or death, and even if the patient recovers fully, the cost to society of induced and prolonged hospital stays and greater patient charges are staggering. It is estimated that at least 25,000 incidents involving drugs administered to a patient by the wrong route occur annually, all of which are the result of preventable human error. The most common cause of confusion in route of administration is the universal nature of medical connectors and injection sites. Most medical connectors and infusion/injection sites are universal couplers that are designed to mate with and therefore accept most syringes and other fluid delivering devices. The most common types of infusion sites are rubber septa designed to be pierced by a needle, and female luer connectors designed to be connected to a syringe or medical tubing with a male luer fitting, either by friction fit or threaded lock. Both types of sites are commonly included in intravenous infusion tubing, on the ends of heparin locks, in stopcocks in all types of intravenous, arterial, epidural, and other type connectors, and even in devices not designed for medication or fluid infusion at all, such as esophageal stethoscopes and urinary catheters. The universal employment of rubber septum injection ports and female luer connectors is directly coupled to thousands of errors in which a medication or fluid designed to be given by one route has inadvertently been given by another route, sometimes with disastrous consequences.

Several additional problems arise from use of current technology. The use of needles for connecting infusion lines and the administration of medicines has led to many cases of needlestick injury and transmission of blood borne infections, including hepatitis and AIDS. The infusion of proper fluids through the needle and coupler is also prone to inadvertent failure due to unwanted disconnection of the needle from the rubber

septum. Moreover, repeated piercing of the coupler with the needle can taint the sterile fluid pathway.

The prior art has attempted to address the foregoing concerns by employing needleless systems and locking connectors, but they too are designed as universal
5 connectors which are subject to route of administration errors. For example, a patient may be connected to multiple fluid delivering devices, hence forming multiple fluid pathways. The medical connectors are typically coupled to fluid delivering and receiving devices by universal type connectors, such as luer fittings. Hence, an attending person may accidentally apply a medicament to the wrong fluid pathway since
10 the universal connector accepts or can be coupled to conventional fluid delivering devices.

It is an object of this invention to develop a needleless, relatively safe, locking connector system that is fluid path-specific. That is, the system should allow only infusions or injections of the proper type to be connected to the specific catheter or
15 tubing type. In order to maintain efficiency and ease of locating the proper connectors, especially in an emergency, the types of connectors should be easily determinable by inspection.

Other general and more specific objects of the invention will in part be obvious and will in part appear from the drawings and description which follow.
20

Summary of the Invention

The invention described herein is designed to eliminate, prevent or reduce the occurrence of unwanted or accidental administration of fluids to the wrong fluid pathway through known universal connectors. The present invention addresses this
25 problem by replacing the universal connector with unique specially configured male/female connector pairs, each coded for use with only one type of medical catheter or device (e.g., peripheral intravenous catheter, central venous catheter, arterial catheter, epidural catheter, dialysis catheter).

The present invention specifically describes in one aspect a family of medical
30 connectors designed to attach a medical infusion or injection device to a patient catheter or device. It is comprised of pairs of male-female locking connectors. The mating

surfaces are uniquely indexed so that only complementary halves of the appropriate set connect together. Preferably, the fluid path runs through the length of the connector halves, with complementary shape- and/or size-indexed pieces constructed coaxially with the fluid path in each half connector. When in use, the two halves are pressed together and via a number of possible techniques locked into position, thus completing the fluid path. The ends of the connector halves opposite the mating surfaces can attach to standard luer-type medical connectors, preferably female on one half and male on the other, in order to interpose the mated connector between a catheter or other patient receiving device and an infusion or fluid delivering device, such as an intravenous tubing set or a syringe. In certain specialized applications, female-female, or male-male outer ends can be incorporated; in still others, non-luer fittings may be incorporated, for example to facilitate piercing a vial or intravenous fluid container.

According to another aspect of the invention, one half of the connector can be permanently attached to a catheter, infusion tubing set or syringe. This facilitates use of the device in applications which are especially sensitive to errors in fluid or medication administration, to ensure correct drug administration in emergency situations. In another aspect, a valve can be incorporated into either or both halves of the connector pair which closes the fluid path when the two halves are not mated together, or may incorporate irreversible locking mechanisms to attach the connector half permanently to a catheter, tubing end or syringe.

The present invention also provides for a medical connector suitable for use in coupling a fluid delivering conduit to a fluid receiving conduit, such as a catheter adapted for insertion within a patient. The medical includes first and second connector housing parts having a first end sized to mate with the fluid receiving and delivering conduits and a second end having a selected first surface feature formed thereon. When assembled, the first surface feature of the first housing part couples with the second surface feature of the second housing part to form a fluid connection therebetween.

According to one aspect, the first surface feature is sized and configured so as to only mate with the complementary shaped second surface feature to prevent another fluid delivering conduit having a differently configured surface feature from being

connected to the fluid receiving conduit, thereby preventing the accidental administration of another fluid to the patient through the first and second housing parts.

According to one practice, the medical connector of the invention can employ a set of first and second medical connector housing parts, each having a differently shaped surface feature. Each housing part can also be adapted for connection at one end to the fluid receiving conduit and has a differently shaped surface feature formed thereon. Additionally, the selected surface feature formed on the second housing parts have a complementary-shaped surface feature. The first and second medical connector housing parts when assembled couple multiple fluid delivering conduits to multiple fluid receiving conduits such that only a particular fluid receiving conduit is coupled to a particular fluid delivering conduit.

According to another aspect, each medical connector housing part further includes a fluid conduit formed therein. When assembled, the first and second fluid conduits allow passage of a fluid therethrough and from the fluid delivering conduit to the fluid receiving conduit.

According to still another aspect, the first and second housing parts form a non-universal medical connector that inhibits universal connectors from coupling the fluid delivering conduit to the fluid receiving conduit. The medical connector can further include a locking element formed on at least one of the first and second medical connector housing parts for securing the housing parts part together.

Brief Description of the Drawings

The foregoing and other objects, features and advantages of the invention will be apparent from the following description and apparent from the accompanying drawings, in which like reference characters refer to the same parts throughout the different views. The drawings illustrate principles of the invention and, although not to scale, show relative dimensions.

Figure 1 is a perspective view of one embodiment of a medical connector incorporating a selectively configured connection mechanism employing both raised and recessed surface features according to the teachings of the present invention.

Figure 2 is a perspective view of the medical connector of Figure 1 disposed in a closed or assembled position.

5 Figure 3 is an end view of the two half portion of a medical connector illustrating another embodiment of the connection mechanism in accordance with the teachings of the present invention.

10 Figure 4 is an unassembled perspective view of another embodiment of the medical connector in accordance with the teachings of the present invention.

Figures 5A through 5D illustrate various constructions of the connection mechanism in accordance with the teachings of the present invention.

15 Figures 6A through 6C illustrate various constructions of a locking mechanism suitable for use with the medical connector of the present invention.

Figures 7A through 7D illustrate the manner in which the medical connector of the present invention can be coupled to various fluid delivering or receiving devices.

20

Description of the Illustrated Embodiment

This present invention involves one or more, such as a family, of medical connectors with male and female halves which are shape- and/or size-indexed so that only complementary pairs of connectors may be coupled and then employed to deliver a fluid to a patient along a selected fluid pathway. The connectors of the present invention help avoid accidental administration of a fluid to the wrong fluid pathway by ensuring that fluid delivering devices can only be connected to a fluid receiving device having a specific configuration. The present invention may be adapted to many different medical applications in the field of medical connectors, injection apparatus, and infusion devices.

30

Figure 1 shows a perspective view of two general medical connector portions, designated as a first male medical connector portion 1 and a second female medical connector portion 3, which incorporate in their first ends, respectively, a protuberance 15 and a cavity 25 complementary in shape to the protuberance. These surface features 5 allow the two connector halves to fit together in a fluid-tight seal, as shown in Figure 2. A fluid path runs through the long axis 4 of the first portion 1 and the second portion 2. Specifically, the medical connector portion 1 includes a central fluid lumen 10 that extends longitudinally therethrough from one end to the other. Likewise, the other medical connector portion 3 includes a central fluid lumen 60 that passes longitudinally 10 therethrough. When assembled, the fluid lumens 10, 60 are disposed in registration with one another to form an intermediate fluid pathway that connects a fluid delivering device to a fluid receiving device.

The illustrated first medical connector portion 1 has a surface feature formed on a mating end, such as the raised protuberance 15. The protuberance 15 can have many 15 shapes, and as illustrated is an annulus having an outer, flattened surface 5 that is disposed generally perpendicular to the long axis 4 of the connector 1 and the lumen 10. The second medical connector 3 has a complementary shaped surface feature, such as recess or cavity 25, which seats the protuberance 15 of the first connector portion 1. The recess 10 ends in a floor stop 65 which is designed to stop the advance of the 20 protuberance 15 when disposed within the recess. A central lumen 65 forms a second fluid pathway within the connector 3 and extends substantially from the recessed first end to the opposite end.

The mateable complementary shaped surface features 15,25 of the medical connectors are designed to be incompatible with conventional type fittings, such as luer 25 taper fittings, which are a family of friction-fit, locking connectors of standardized size and shape, widely used in medical applications, and well known in the art. The surface features can have a variety of shape and sizes, such as illustrated in Figures 5A-5D.

The illustrated first medical connector 1 includes an outer housing having a recessed end which forms an outer annulus 26 that is coaxially disposed about the 30 protuberance 15. The outer annulus 26 includes a number of channels 28 formed therein, which terminate in a lock or key portion 29, formed towards an intermediate

portion of the medical connector. The medical connector 1 can further include a series of circumferential grooves 32 formed about the outer body portion of the connector. The grooves are preferably sized to seat a locking arm, Figure 6C, that can be formed on the other medical connector part for locking or securing the two connector components
5 together to form a fluid-tight seal.

With further reference to Figure 1, the medical connector portion 1 further includes a stepped outwardly extending housing portion 34, and a further outwardly extending portion 36 that extends along the longitudinal axis 4. This portion terminates in a flange or collar 55 adapted to connect with a fluid receiving or delivering device.

- 10 10 The other medical connector part 3 includes an outer housing portion 38 configured complementary to the mating end 20 of the other connector portion 1, so as to be able to couple thereto in a fluid sealing arrangement. Specifically, the outer housing portion 38 of the medical connector 3 terminates in a tab portion 35 that is designed to seat within the key portion 29 of the other medical connector portion 1. The connector 3 is further
15 15 tapered at an intermediate portion 42 and includes a cut-out portion 44. The connector terminates in a chamfered end 70 having an axially extending connector 50.

The two medical connector portions 1, 3 when mated together can either be held together by a friction fit arrangement, by the key locking scheme illustrated in Figure 1, or by a number of other locking schemes, as shown in Figures 6A through 6C. The
20 20 illustrated locking scheme involves seating the protuberance 15 in the recess 25 such that the mating portions of the two connectors are coaxially arranged. Furthermore, the outer housing 38 of connector 3 has an end 30 that seats within the space or channel 31 formed between the protuberance 15 and the outer annulus 26. Likewise, the outer end 20 of the protuberance is coaxially arranged with and seats about the outer surface or shell 38. In
25 25 order to assemble the connector parts, the portions 1 and 3 are pressed together, and the outer housing portions rotated around its long axis so that the tab 35 engages and locks with the complementary key portion 29. The assembled medical connector portions form a secure, fluid-tight medical connector 40 that couple together various fluid devices, such as catheters, needles, or syringes connected to the luer fittings 55 and 50,
30 30 as illustrated in Figure 2.

The illustrated medical connector portions 1, 3 of the invention are designed to be application or path-specific. The male or first connector portion 1 of the medical connector 40 is configured to mate with only one type of mating surface, although selected others are also contemplated, and will not mate with other female type 5 connectors. Thus a connector designated, for example, for epidural catheter injections is generally incapable of connection to a syringe intended for intravenous injection absent the specially configured surface feature. The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from distinctive markings on the outer surfaces of the half connectors. These 10 markings can include textured features, color coding and/or text labels, such as labels 70.

Each medical connector portion 1, 3 has an end 55, 50 opposite the mating surface or ends 20, 30 that are adapted to mate to a fluid delivering device, such as catheters, needles, syringes or other medical devices. In the illustrated connector of Figure 1, the ends 55, 50 can be standard luer taper fittings, either slip or locking type, 15 which are easily connected to the fluid delivering or receiving devices. Luer type fittings are well known and well characterized, and need not be described further herein. The use of safe and secure luer-type fluid fittings allow the safety medical connector 40 to be interposed between standard medical components now in widespread use. The medical connector 40 can also be permanently incorporated into various catheters, 20 connectors, syringes, tubing sets, and other devices designed for patient connection, as shown in Figures 7A-7D.

Figure 3 illustrates another type of connector design suitable for use in accordance with the present invention. The illustrated connector includes two connector portions 60, 62 designed to join together to form a fluid-tight seal for the injection or infusion of a medication or medical fluid, or alternatively for the evacuation of a body 25 fluid, via a catheter or device placed into the patient's vein, artery, epidural or spinal space, or other body compartment. The medical connector portions 60 includes a quadrilateral shaped raised surface feature 66 extending from one end 60A. The connector includes a fluid lumen 68 formed therein that extends between the connector 30 ends. The other connector portion 62 has a recessed surface feature 72 complementary in shape to the raised feature in order to accommodate and properly seat the raised

feature to form a fluid tight seal. According to one practice, the end region 62A includes a cavity 72 that has a floor portion 74. The floor portion is apertured with an opening that defines the fluid lumen 70. The lumen extends between the connector ends.

When assembled, the protuberance 66 seats within the cavity 72 to dispose the 5 lumen 68 in fluid communication with the lumen 70 to form a continuous fluid path along the assembled connector and between, for example, an infusion or injection source and a patient catheter. The two connector portions 60, 62 can be locked together using a variety of different schemes as discussed below. The locked pair of medical connector portions can include additional connection sites (such as luer fittings) on the ends 10 opposite the mating surfaces 60A, 62A which allow the device to be inserted between the patient and the injection, infusion, or evacuation source. For example, the basic design can consist of standard luer taper fittings attached to each medical connector half. Therefore, an epidural catheter 80 can be connected via its female luer hub adapter 82 to a male luer fitting 84 coupled to one end of a medical connector, generally illustrated as 15 medical connector portion 86, configured in accordance with the present invention. The connector 86 couples to the other connector half to complete the medical connection. According to one practice, the illustrated connector 86, when not coupled to its mating connector, generally cannot be connected to any standard syringe or medical tubing which is devoid of a complementary surface feature.

20 Figures 5A through 5D illustrate still other embodiments of the surface features which can be formed on the mating ends of the medical connectors in accordance with the present invention. In each case, a complementary pair of protuberances and recesses are incorporated into the medical connectors. In Figure 5A, the protuberances can have a variety of geometric shapes, which are arranged coaxially around the lumen 10. The 25 shapes of the surface features can further include a triangle 100, square 105, pentagon 110, hexagon 115, or other regular polygon or quadrilateral shape. As is readily apparent to those of ordinary skill, each illustrated surface feature can replace the cylindrical protuberance 15 of Figure 1. The raised surface features fit into a complementary shaped and sized cavity formed in the other medical connector half.

Figures 5B and 5C illustrate employing raised surface features that have varying sizes. In these instances, the lumen 10 is surrounded by a cylindrical protuberance of small 130, intermediate 135, or larger 140 diameter, or alternatively a regular polygon of small 145, intermediate 150, or larger 155 size. Figure 5D illustrates employing radial 5 projections in an outer surface of the connector half, to effectuate radial pin indexing. In this configuration, radially spaced pins 160 are arranged circumferentially about the protuberance 15. These pins uniquely mate with complementary slots 165 arranged radially within the walls of the cavity 25 formed in the other connector half.

The foregoing medical connectors can be fashioned from hard plastic or other 10 suitably minimally deformable material, so that incompatible connector halves cannot mate in a fluid-tight manner. Attempts to do so will cause the fluid path to leak, preventing inadvertent injection. Integrity of the fluid path can be ensured either by a tight friction fit between the complementary connector parts, or by the inclusion of an integral rubber or other deformable gasket on the male portion of the connector pair. 15 This gasket would be slightly larger in its non-deformed state than the complementary female half connector's cavity, so that when the two connectors are mated, the gasket deforms and causes a tight seal.

Two complementary medical connector portions can be joined together to form a complete medical connector. Once assembled, the connector portions can be locked into 20 the mated or joined position in a variety of ways. Some examples of locking arrangements suitable for use with the medical connector of the present invention are illustrated in Figures 1 and 6A through 6C. As described above, the connector portions 1 and 3 of Figure 1 include a key and tab engagement arrangement to secure the connector halves together. Figure 6A illustrates a pair of medical connectors 200 and 25 205 which can be assembled and held together with a simple friction fit. In this configuration, the mating portion of connector 200 is slightly smaller in size than the complementary connector 205 so that when engaged, sufficient force is required to separate the connector pair such that ordinary injection pressures do not separate them. Specifically, the medical connectors 200, 205 require some amount of force to separate 30 the connector portions. The tolerances of the two mating medical connector portions are

such that the pressure in the fluid delivering or receiving conduits attached to the connector are generally insufficient to drive the pair apart.

Figure 6B illustrates another of securing or locking the connectors 300 and 320 together. In this embodiment, the connector 305 includes a stepped axially extending lip portion 305 formed on the mating end of the connector. The lip of the larger connector includes a slightly raised portion or detent 306 extending radially inwardly towards or into the lumen. The lip 305 is adapted for engagement with a complementary channel or indent formed in the mating end of the other connector 320, which is of slightly smaller diameter. The two connector halves can lock together with a pushing action, with one side designed to pass over the other. When assembled, the smaller connector 320 is pushed within the larger connector half 300 until the lip 305 engages the complementary indent 310, thereby securing the connector portions together.

Figure 6C shows the similar arrangement of two outer housings of slightly different diameters 300 and 320 with slots 400 formed on the outer surface of connector 320, which engage slightly spreadable or deformable fingers 405 attached to and extending from the other connector half.

Still other embodiments of securing mechanisms include providing connector portions that contain a central fluid lumen, and ending in luer or other fittings for connection to medical tubing, syringes, or catheters. The entire inner portion of the connector is adapted to spin freely around the axis of the fluid lumen. When assembling together the two medical connector halves, the inner portions of the connectors mate together, and then the outer housing portions of the connectors are twisted together to lock them. Several mechanisms for locking the outer portions are possible. The two outer housings could be designed with complementary deformable tabs and slots which engage when twisted together, threaded ends which screw together, or fingers on one part which lock into slots on the other part, as described above in connection with Figures 6A through 6C. Another embodiment of a securing mechanism can include configuring the inner mating portions of the connector portions so as not to spin along the axis of the fluid lumen.

As described above, the foregoing medical connectors function as a basic interface between standard fluid delivering and receiving devices, such as standard catheters and infection sources, via standard medical luer fittings. In the usual application, one connector portion of the present invention contains at its non-mating 5 end a male luer fitting with or without a standard twist-lock feature, and the other connector contains a similarly positioned female luer fitting. In certain specialized applications, twin female or male luer adapters could be incorporated.

This medical connectors of the invention can also be fitted with connectors at the non-mating ends that allow its connection to other medical devices and containers. In 10 one important embodiment of this invention, one connector half is permanently fused to or incorporated into a standard medical infusion device, so that use of a complementary connector is mandatory to access the catheter or device. For example, an epidural catheter adapter, which typically grips a 18 to 21 G epidural catheter and ends in a female luer fitting, is mounted to one end of the medical connector half. Only a syringe 15 or tubing set incorporating or fitted with the complementary half connector can be used with this type of epidural catheter. Any catheter, injection adapter, tubing set, syringe, or device connecting to a patient catheter and currently using luer universal connectors can be adapted to incorporate half connectors of a given type from the present invention. The invention thus allows a family of safety injection sources and catheters to replace 20 the inherently less safe universal connectors in wide use today.

The foregoing safety medical connectors are designed to be interposed between existing devices for medical infusions, injections, or aspirations. An additional feature of the present invention is the fusion of a half connector as illustrated in Figure 1 into a standard medical connector or device. Figures 7A through 7D illustrate the 25 incorporation of a safety connector half into an epidural catheter connector 500, which in turn is connected to an epidural catheter 505. Any of the mating and locking configurations of the present invention, for example the rectangular surface feature 510, can be incorporated into the end of the epidural catheter connector. The epidural catheter connector in turn mates with a complementary safety connector half 520. This 30 connector half includes a complementary shaped surface feature that ensures that only

medications intended for epidural delivery are injected through the epidural catheter, since only a specific surface feature 510 can mate with the connector half 520.

Figure 7B illustrates another example of attachment mechanisms adapted for use with the medical connector of the present invention. The illustrated medical connector 5 can be coupled to a hollow sharpened spike designed for piercing bags of intravenous fluids, blood products, or premixed intravenous medications; a connector to feeding tubes; or a connector for certain specialized catheters used in peritoneal dialysis. Specifically, a half connector 1 is incorporated into a tubing set for infusion of fluids or medications into a patient, typically comprised of tubing 540 and a spike 535 for 10 piercing a container of fluid or medication, which can be seen to be infusing through a transparent drip chamber 530. In still another configuration, as shown in figure 7C, a half connector 1 is incorporated into a syringe 545. In another embodiment, as shown in Figure 7D, a half connector 1 is incorporated into a three-way stopcock 550 which allows entry of medication or withdrawal of fluids or medications from a tubing set 555.

15 Other variations of the basic design of the medical connector of the present invention are contemplated by this invention and thus form part of the description. First, one medical connector half may be fused permanently or incorporated into an existing medical infusion or injection device. For example, a syringe prefilled with a medication that can only be given safely by a certain route could be fashioned with a half connector 20 on its end. Only by mating with a catheter fitted with the appropriate complementary connector part (perhaps also permanently mounted) can the injection be given. Tubing sets designed for particular applications such as epidural anesthetic infusions can be fashioned with injection sites which only connect to other complementary connector parts. Thus, while allowing simple and needless injection of additional medications, 25 inadvertent injection of inappropriate medications would be significantly less likely, and hence prevented.

In other designs, either or both medical connector portions can be fitted with a valve which is disposed in a normally closed position but is opened by appropriate mating with a complementary connector. A spring loaded mechanism closes the valve 30 whenever the connector parts are disconnected, preventing fluid leaks and contamination of the lumen. The connector portions can also be configured to connect to standard

medical infusion devices or catheters via essentially irreversible mechanisms so that, once connected, the safety of the device cannot be subverted by removing one half connector to restore a universal connection. An example of such an application is the preservation of one lumen of a central venous catheter exclusively for infusion of

5 parenteral nutrition solutions. Commonly, warning labels or adhesive tape are placed over the rubber septum cap on the end of such a port, but these are easily subverted. A locked half connector from the present invention would all but eliminate this problem. Two such methods for locking the connectors are as follows. First, a modified screw-type male luer adapter with a wedge shaped enlargement incorporated into the screw

10 threads may be substituted for an ordinary male luer adapter. A tab on the circumferential edge of a standard female luer adapter normally engages the threads in the male screw-type luer connector. When it meets the wedge in the threads of the modified adapter described here, it follows the ramped edge of the wedge, slightly deforming the threaded connector until it crosses the end of the wedge and returns to the

15 threaded path. Because the wedge is placed so that the narrow end is contacted first during clockwise (tightening) rotation of the male luer adapter, unscrewing of the adapter once the wedge has been passed will be very difficult or impossible.

A second method for locking the present invention to an existing female luer adapter is to dispose a coaxial collar about the adapter. The inner male screw adapter is

20 of standard design, and an outer collar is adapted to spin about its long axis (which includes the fluid path). Teeth arranged in the space between the male luer screw portion and the outer collar allow the outer collar to turn the inner male luer screw fitting only in the clockwise direction. Counterclockwise rotation is impossible because the teeth do not engage, and therefore once the modified male luer adapter has been screwed

25 onto the female luer adapter, unscrewing them is difficult or impossible.

Still another modification of the connector of the invention is a family of accessory caps for covering the unmated half connectors of the basic device or its modifications as described elsewhere in this section. These caps have inner surfaces complementary to the male or female connector halves and insert over the mating

30 surface of the connector half, preferably with a friction-fit.

This invention is designed to be used in both routine and emergency medical care. As such, simple and rapid identification of the complementary half connectors is important. Besides inspection of the mating surfaces themselves, a variety of techniques may be utilized to ease identification of the connectors (see Section 5). The preferred 5 implementation of this technology into medical practice would involve standardization of the various connector types to be used only for certain catheters. For example, there could be one type only used for epidural catheters, one for peripheral intravenous catheters, and another for central venous catheters.

In certain applications, the medical connectors of the present invention may be 10 advantageously employed with indwelling lines, i.e., central and peripheral intravenous lines, to offer selectivity relative to the fluid delivering device. For example, a syringe filled with a medicament that can be safely administered both peripherally and centrally, such as morphine, should be able to mate, via the medical connectors of the present invention, with the central and peripheral intravenous lines. In this embodiment, a pair 15 of first housing parts having the same surface feature are coupled to both fluid receiving or indwelling pathways. The syringe (fluid delivering device) has coupled thereto a connector half that has a shape complementary to the shape of the other surface feature, thus enabling this connector and syringe to couple to both fluid pathways, and nothing else, if desired. However, a medicament that is not safely administered peripherally, 20 such as potassium chloride, can be pre-filled in a syringe that could mate only with the connector half associated with the central line. Hence, the central intravenous line or pathway mates with both the central and peripheral compatible syringes, but the peripheral line connector only mates with the peripheral syringe. The central and peripheral lines can be manufactured with such fittings as integral parts, or as 25 irreversibly attachable connectors when site specificity is warranted.

The general concept embodied in this technology, in summary, is that medical connectors are made path-specific rather than universal. This general description is of a pair of connectors disposed between standard fluid delivering and receiving devices.

It will thus be seen that the invention efficiently attains the objects set forth 30 above, among those made apparent from the preceding description. Since certain changes may be made in the above constructions without departing from the scope of

the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are to cover all generic
5 and specific features of the invention described herein, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described the invention, what is claimed as new and desired to be secured by Letters Patent is:

Claims

1. A medical connector suitable for use in coupling a fluid delivering conduit to a fluid receiving conduit, such as a catheter adapted for insertion within a patient, said
5 medical connector comprising
 - a first medical connector housing part having a first end sized to mate with the fluid receiving conduit and a second end having a selected first surface feature formed thereon, and
 - a second medical connector housing part having a first end configured to mate
10 with the fluid delivering conduit and a second end having a selected second surface feature complementary in shape to the first surface feature of the first housing part, so that when assembled the first surface feature of the first housing part couples with the second surface feature of the second housing part to form a fluid connection therebetween,
 - 15 wherein said first surface feature is sized and configured so as to only mate with the complementary shaped second surface feature to prevent another fluid delivering conduit having a differently configured surface feature from being connected to the fluid receiving conduit, thereby preventing the accidental administration of another fluid to the patient through the first and second housing parts.
- 20
2. The medical connector of claim 1, wherein said first medical connector housing part further includes means forming a first fluid conduit therein, and said second medical connector housing part includes forming a second fluid conduit therein, wherein when said housing parts are assembled, the first and second fluid conduits allow passage of a
25 fluid therethrough and from the fluid delivering conduit to the fluid receiving conduit.

3. The medical connector of claim 1, further comprising
a set of first medical connector housing parts, each housing part being adapted
for connection at one end to the fluid receiving conduit and having a selected surface
feature formed on the other end, each first housing part having a differently shaped
surface feature, and
5 a set of second medical connector housing parts, each housing part being adapted
for connection at one end to the fluid delivering conduit and having a selected surface
feature formed on the other end, each second housing part having a differently shaped
surface feature, each of which is complementary in shape to one of said first surface
features,
10 wherein said first and second medical connector housing parts when assembled
couple multiple fluid delivering conduits to multiple fluid receiving conduits such that
only a particular fluid receiving conduit is coupled to a particular fluid delivering
conduit.
15
4. The medical connector of claim 1, wherein said first surface feature is a
protrusion and said second surface feature is a recess.
5. The medical connector of claim 1, wherein said first and second housing parts
20 when assembled form a non-universal medical connector that inhibits universal
connectors from coupling the fluid delivering conduit to the fluid receiving conduit.
6. The medical connector of claim 1, wherein said medical connector further
comprises a locking element formed on at least one of said first and second medical
25 connector housing parts for securing said first connector housing part to said second
medical connector housing part.

7. A method of delivering a fluid from a fluid delivering conduit to patient from a fluid receiving conduit through a selected fluid pathway, said method comprising step of providing a first medical connector housing part having a first end sized to mate with the fluid receiving conduit and a second end having a selected first surface feature formed thereon, and

providing a second medical connector housing part having a first end configured to mate with the fluid delivering conduit and a second end having a selected second surface feature complementary in shape to the first surface feature of the first housing part, so that when assembled the first surface feature of the first housing part couples with the second surface feature of the second housing part to form a fluid connection therebetween,

wherein said first surface feature is sized and configured so as to only mate with the complementary shaped second surface feature to prevent another fluid delivering conduit having a differently configured surface feature from being connected to the fluid receiving conduit, thereby preventing the accidental administration of another fluid to the patient through the first and second housing parts.

8. The method of claim 7, further comprising the step of forming a first fluid conduit within said first medical connector part and a second fluid conduit within said second medical connector part.

9. The method of claim 8, further comprising assembling said housing parts such that the first and second fluid conduits allow passage of a fluid therethrough and from the fluid delivering conduit to the fluid receiving conduit.

10. The method of claim 7, further comprising the steps of
providing a set of first medical connector housing parts, each housing part being
adapted for connection at one end to the fluid receiving conduit and having a selected
surface feature formed on the other end, each first housing part having a differently
5 shaped surface feature, and
providing a set of second medical connector housing parts, each housing part
being adapted for connection at one end to the fluid delivering conduit and having a
selected surface feature formed on the other end, each second housing part having a
differently shaped surface feature, each of which is complementary in shape to one of
10 said first surface features,
wherein said first and second medical connector housing parts when assembled
couple multiple fluid delivering conduits to multiple fluid receiving conduits such that
only a particular fluid receiving conduit is coupled to a particular fluid delivering
conduit.

15

11. The method of claim 7, further comprising the step of forming a non-universal
medical connector that inhibits universal connectors from coupling the fluid delivering
conduit to the fluid receiving conduit from said first and second medical connector parts.

20 12. The method of claim 7, further comprising the step of providing a locking
element on at least one of said first and second medical connector housing parts for
securing said first medical connector housing part to said second medical connector
housing part.

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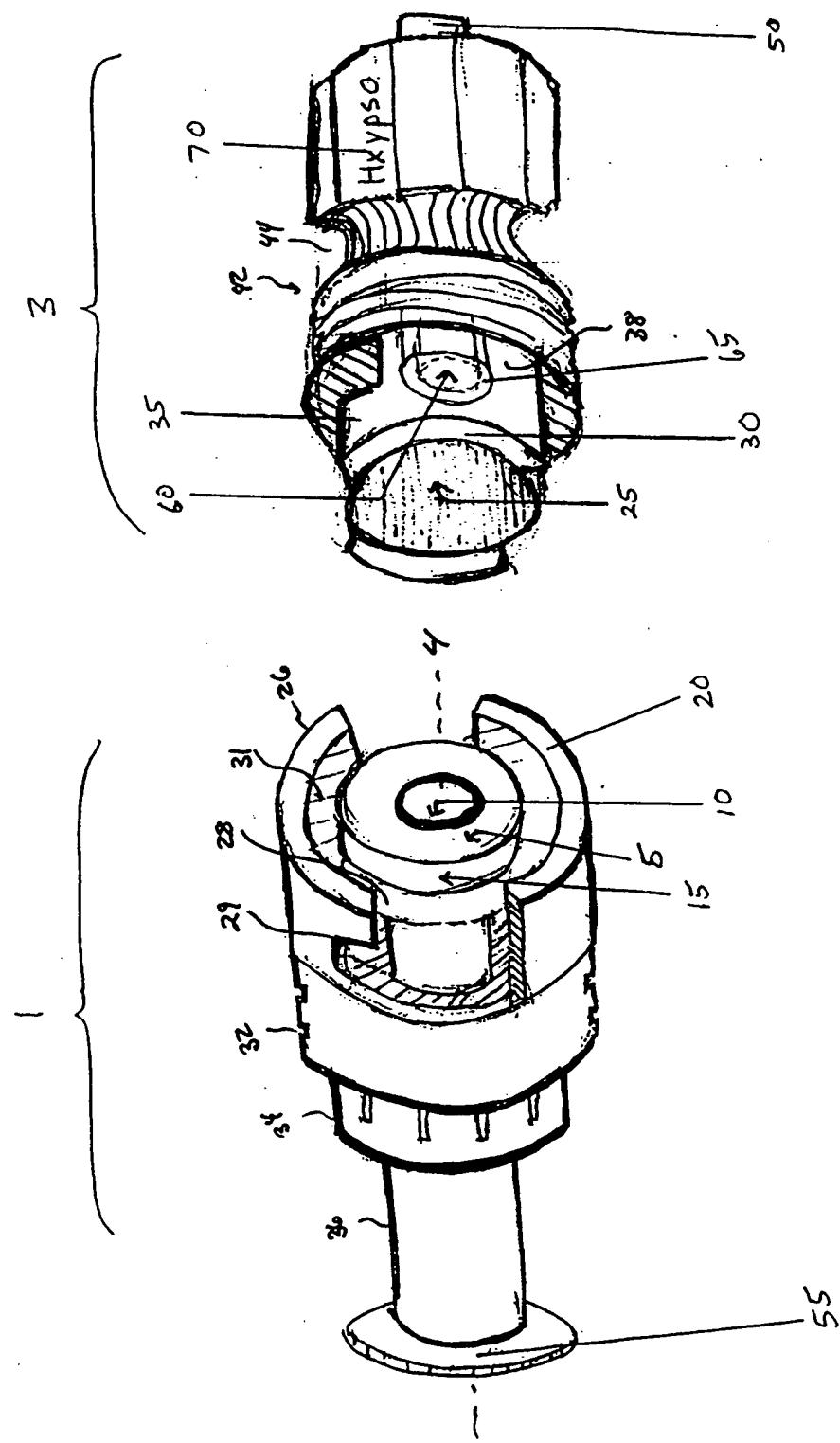


FIGURE 1

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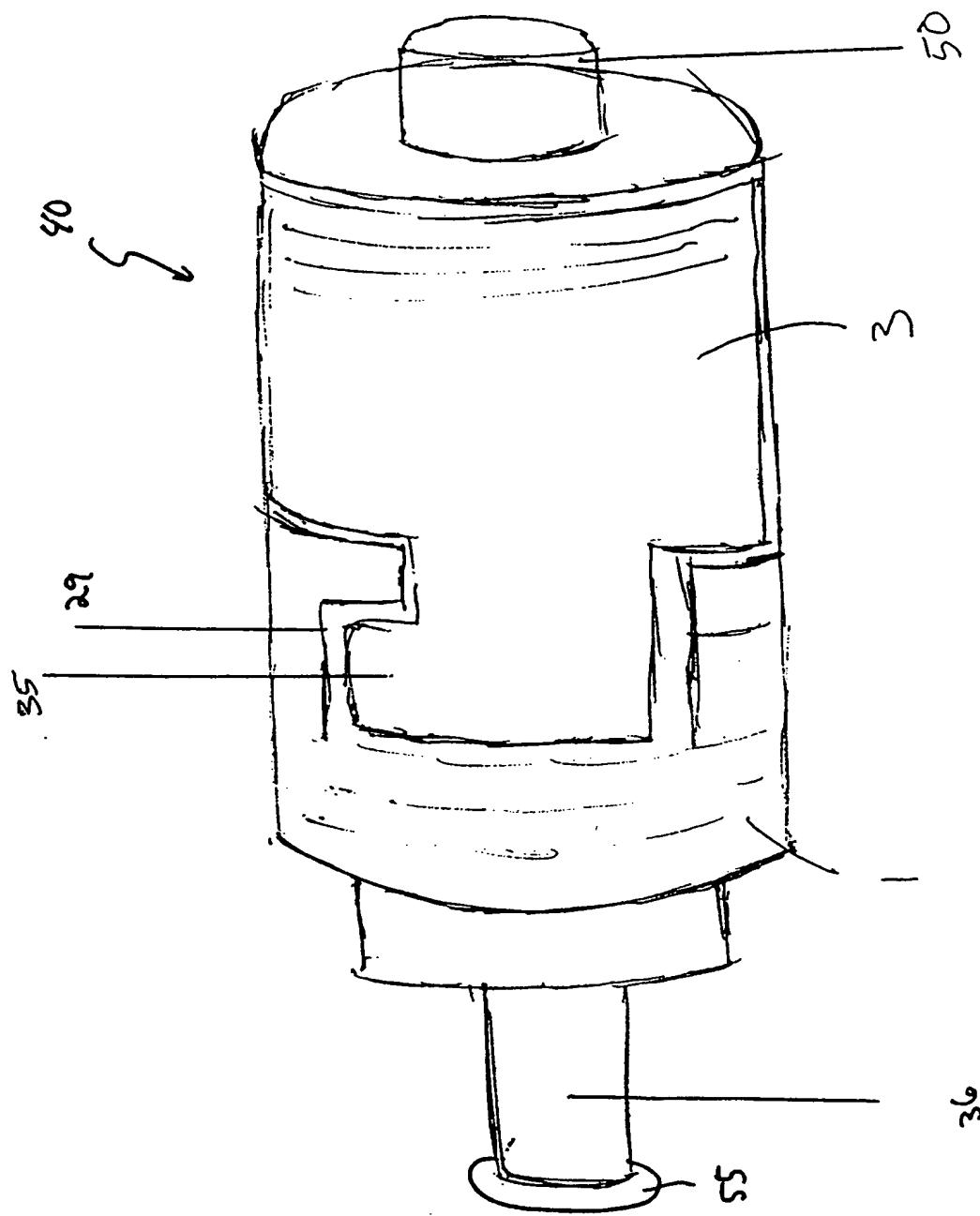


FIGURE 2

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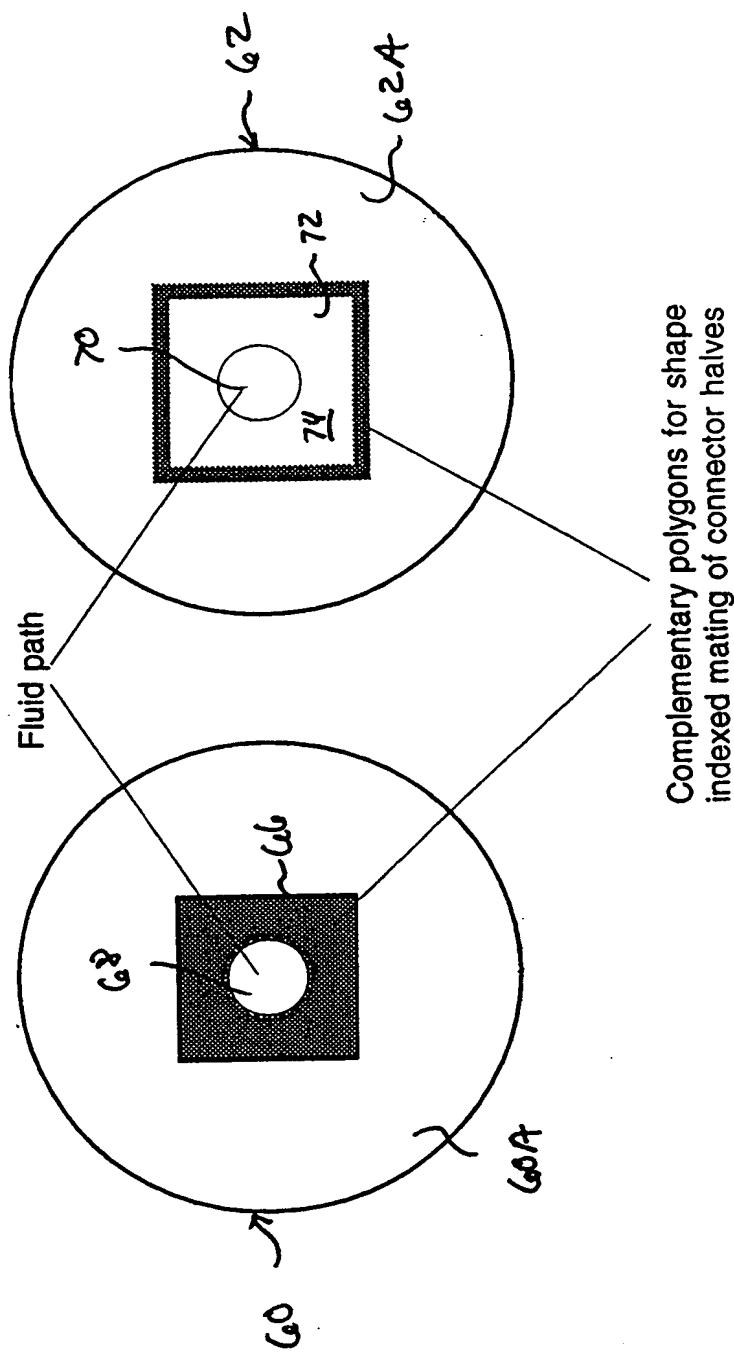


FIGURE 3

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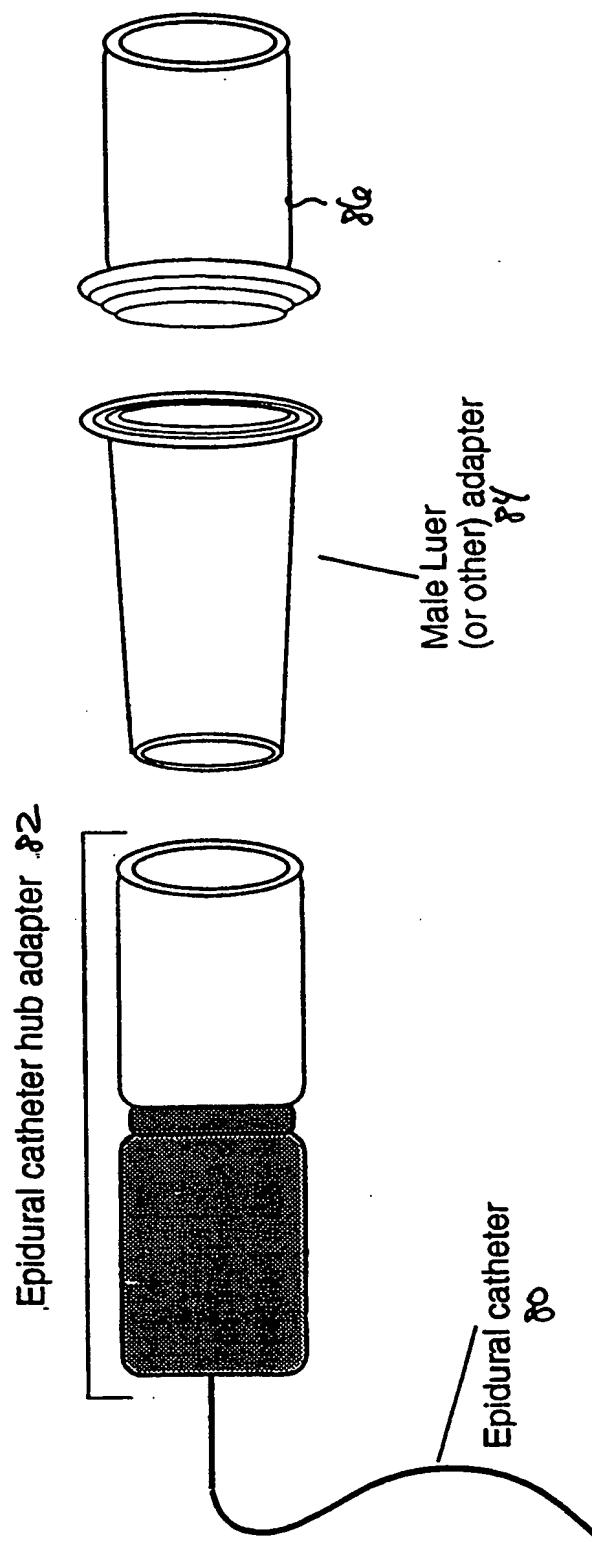
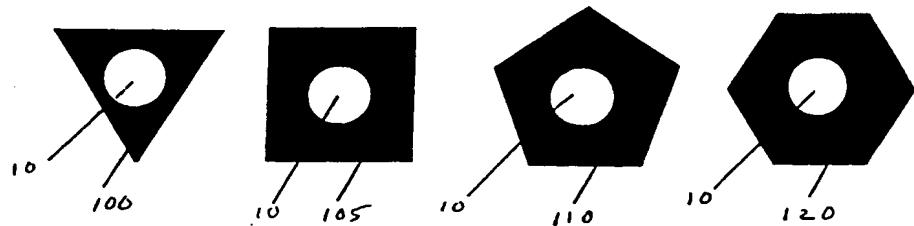
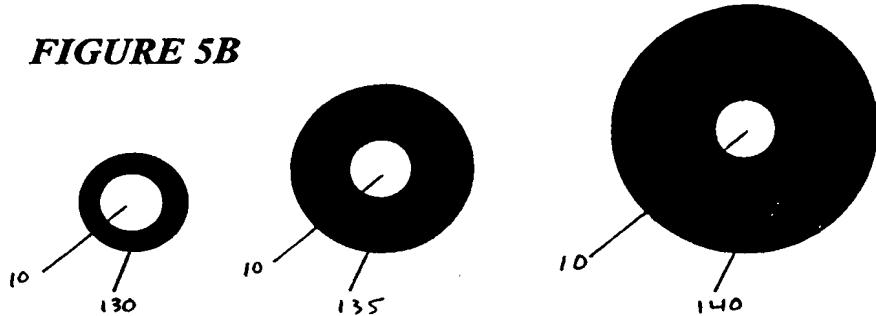
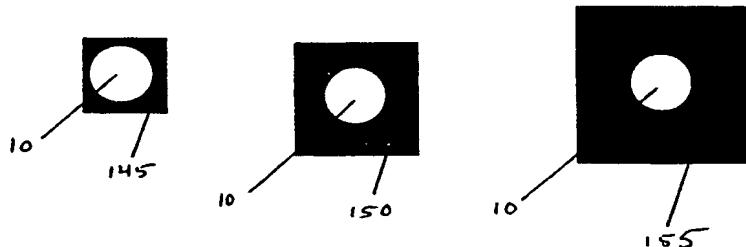
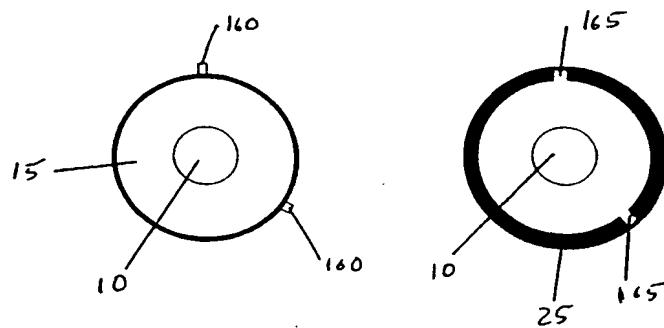
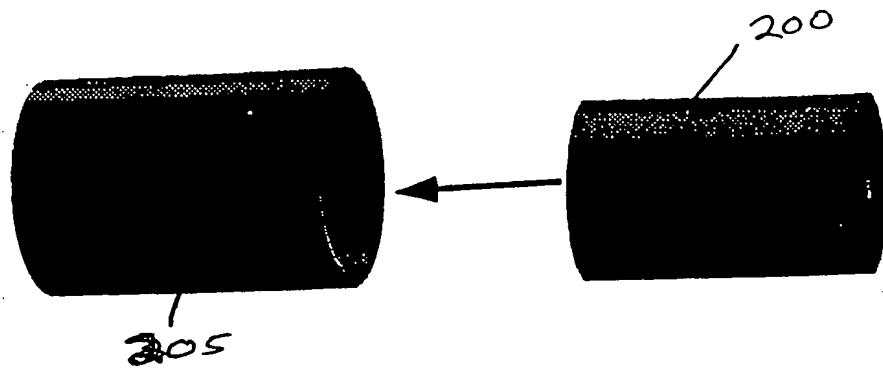
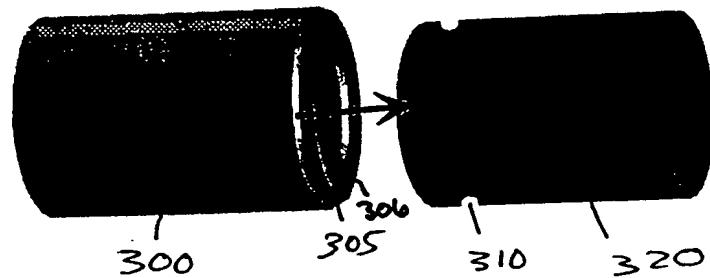
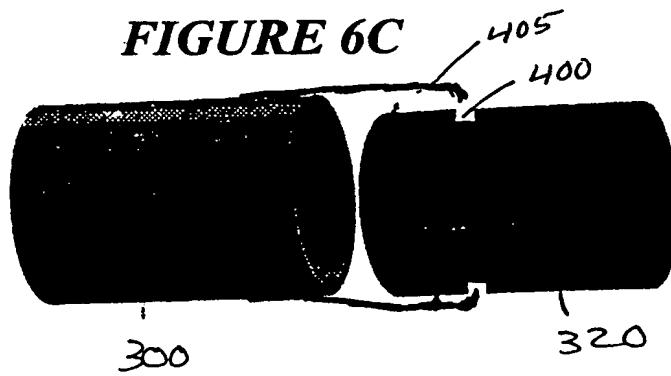


FIGURE 4

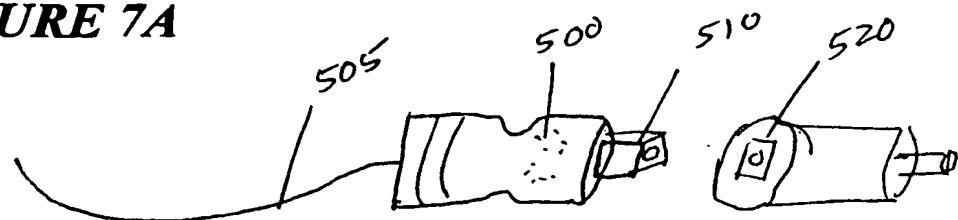
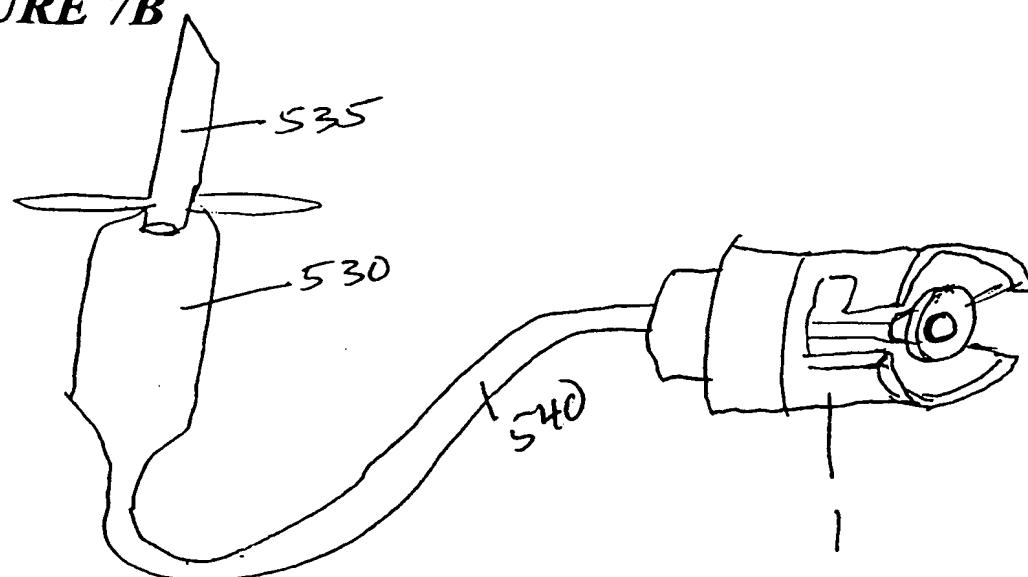
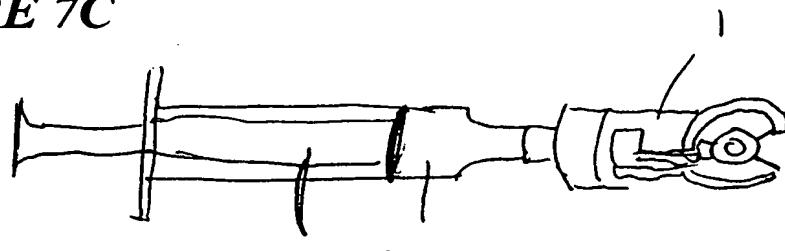
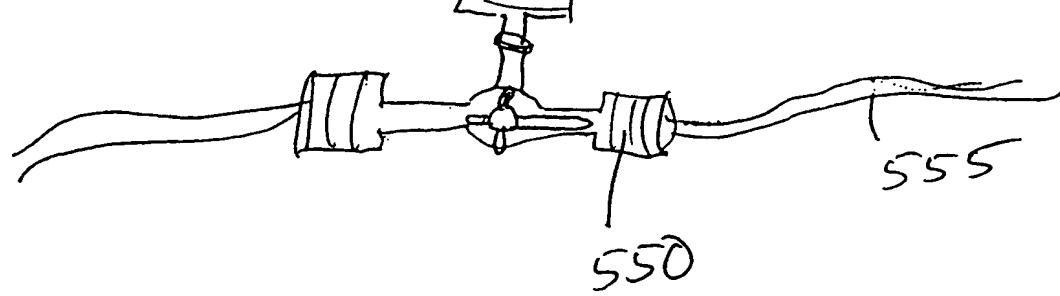
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FIGURE 5A**FIGURE 5B****FIGURE 5C****FIGURE 5D**

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FIGURE 6A**FIGURE 6B****FIGURE 6C**

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FIGURE 7A**FIGURE 7B****FIGURE 7C****FIGURE 7D**

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12878

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 619 640 A (POTOLSKY ET AL.) 28 October 1986 (1986-10-28) column 2, line 65 -column 5, line 65 figures 2-5 ---	1,2,4-6
X	EP 0 774 270 A (DELVIGO) 21 May 1997 (1997-05-21) column 2, line 25 - line 55 column 3, line 39 -column 4, line 44 figures 2,3 ---	1,2,4-6
X	US 4 150 673 A (WATT) 24 April 1979 (1979-04-24) column 2, line 65 -column 3, line 25 figures 1-3 ---	1-3



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

30 September 1999

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12878

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 217 055 A (KAWASUNI LABORATORIES, INC.) 8 April 1987 (1987-04-08) page 8, line 4 -page 9, line 1 figures 1-3,15 -----	1,2,4-6

INTERNATIONAL SEARCH REPORT

national application No.

PCT/US 99/ 12878

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 7-12 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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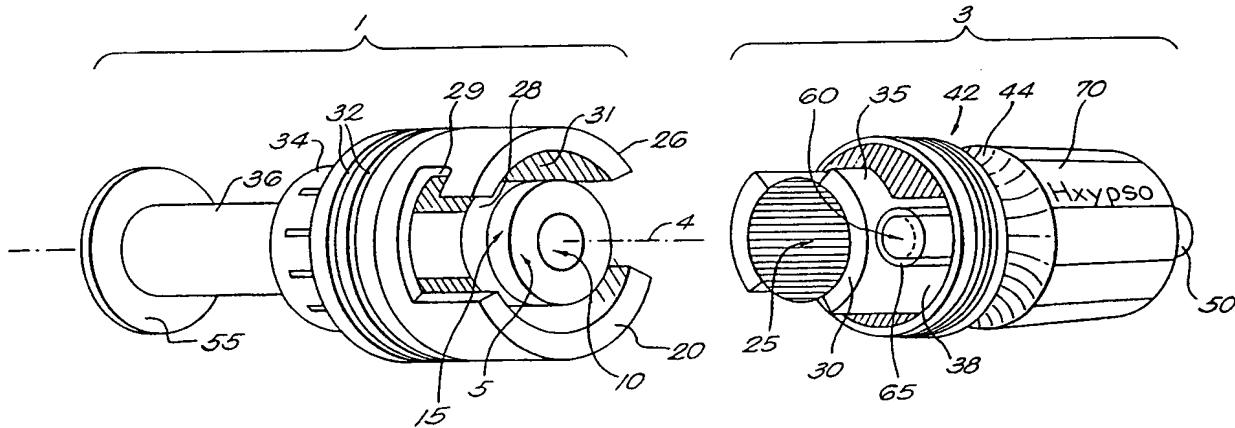
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 39/10	A1	(11) International Publication Number: WO 99/64103 (43) International Publication Date: 16 December 1999 (16.12.99)
(21) International Application Number: PCT/US99/12878		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
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(30) Priority Data: 09/094,433 8 June 1998 (08.06.98) US		
(71) Applicant: QD ENTERPRISES, LLC [US/US]; Suite 202, 30 Firebrick Road, Sharon, MA 02067 (US).		
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(74) Agents: LAURENTANO, Anthony, A. et al.; Lahive & Cockfield, LLP, 28 State Street, Boston, MA 02109 (US).		

(54) Title: SAFETY INDEXED MEDICAL CONNECTORS



(57) Abstract

A medical connector adapted for placement between a catheter and a medical infusion or injection source includes a pair of interlocking half medical connector portions, one side of which attaches to the infusion source and the other side of which is coupled to the catheter connected to the patient. The connection to the catheter and the infusion source can be via standard medical luer taper fittings, with or without specially designed locking mechanisms that prevent inadvertent disconnection. The medical connector itself is uniquely shaped and includes a raised surface feature and a recessed surface feature formed on the medical connector portions.

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SAFETY INDEXED MEDICAL CONNECTORS

Background of the Invention

The present invention relates to fluid connectors, and more particularly to fluid
5 connectors used in medical environments and designed to ensure the correct and appropriate administration of medicaments to a patient.

Errors in prescribing and delivering medications to patients are, unfortunately, common in medical practice. Many of these mistakes result in patient injury or death, and even if the patient recovers fully, the cost to society of induced and prolonged
10 hospital stays and greater patient charges are staggering. It is estimated that at least 25,000 incidents involving drugs administered to a patient by the wrong route occur annually, all of which are the result of preventable human error. The most common cause of confusion in route of administration is the universal nature of medical connectors and injection sites. Most medical connectors and infusion/injection sites are
15 universal couplers that are designed to mate with and therefore accept most syringes and other fluid delivering devices. The most common types of infusion sites are rubber septa designed to be pierced by a needle, and female luer connectors designed to be connected to a syringe or medical tubing with a male luer fitting, either by friction fit or threaded lock. Both types of sites are commonly included in intravenous infusion tubing, on the
20 ends of heparin locks, in stopcocks in all types of intravenous, arterial, epidural, and other type connectors, and even in devices not designed for medication or fluid infusion at all, such as esophageal stethoscopes and urinary catheters. The universal employment of rubber septum injection ports and female luer connectors is directly coupled to thousands of errors in which a medication or fluid designed to be given by one route has
25 inadvertently been given by another route, sometimes with disastrous consequences.

Several additional problems arise from use of current technology. The use of needles for connecting infusion lines and the administration of medicines has led to many cases of needlestick injury and transmission of blood borne infections, including hepatitis and AIDS. The infusion of proper fluids through the needle and coupler is also
30 prone to inadvertent failure due to unwanted disconnection of the needle from the rubber

septum. Moreover, repeated piercing of the coupler with the needle can taint the sterile fluid pathway.

The prior art has attempted to address the foregoing concerns by employing needleless systems and locking connectors, but they too are designed as universal connectors which are subject to route of administration errors. For example, a patient may be connected to multiple fluid delivering devices, hence forming multiple fluid pathways. The medical connectors are typically coupled to fluid delivering and receiving devices by universal type connectors, such as luer fittings. Hence, an attending person may accidentally apply a medicament to the wrong fluid pathway since the universal connector accepts or can be coupled to conventional fluid delivering devices.

It is an object of this invention to develop a needleless, relatively safe, locking connector system that is fluid path-specific. That is, the system should allow only infusions or injections of the proper type to be connected to the specific catheter or tubing type. In order to maintain efficiency and ease of locating the proper connectors, especially in an emergency, the types of connectors should be easily determinable by inspection.

Other general and more specific objects of the invention will in part be obvious and will in part appear from the drawings and description which follow.

20

Summary of the Invention

The invention described herein is designed to eliminate, prevent or reduce the occurrence of unwanted or accidental administration of fluids to the wrong fluid pathway through known universal connectors. The present invention addresses this problem by replacing the universal connector with unique specially configured male/female connector pairs, each coded for use with only one type of medical catheter or device (e.g., peripheral intravenous catheter, central venous catheter, arterial catheter, epidural catheter, dialysis catheter).

The present invention specifically describes in one aspect a family of medical connectors designed to attach a medical infusion or injection device to a patient catheter or device. It is comprised of pairs of male-female locking connectors. The mating

surfaces are uniquely indexed so that only complementary halves of the appropriate set connect together. Preferably, the fluid path runs through the length of the connector halves, with complementary shape- and/or size-indexed pieces constructed coaxially with the fluid path in each half connector. When in use, the two halves are pressed together and via a number of possible techniques locked into position, thus completing the fluid path. The ends of the connector halves opposite the mating surfaces can attach to standard luer-type medical connectors, preferably female on one half and male on the other, in order to interpose the mated connector between a catheter or other patient receiving device and an infusion or fluid delivering device, such as an intravenous tubing set or a syringe. In certain specialized applications, female-female, or male-male outer ends can be incorporated; in still others, non-luer fittings may be incorporated, for example to facilitate piercing a vial or intravenous fluid container.

According to another aspect of the invention, one half of the connector can be permanently attached to a catheter, infusion tubing set or syringe. This facilitates use of the device in applications which are especially sensitive to errors in fluid or medication administration, to ensure correct drug administration in emergency situations. In another aspect, a valve can be incorporated into either or both halves of the connector pair which closes the fluid path when the two halves are not mated together, or may incorporate irreversible locking mechanisms to attach the connector half permanently to a catheter, tubing end or syringe.

The present invention also provides for a medical connector suitable for use in coupling a fluid delivering conduit to a fluid receiving conduit, such as a catheter adapted for insertion within a patient. The medical includes first and second connector housing parts having a first end sized to mate with the fluid receiving and delivering conduits and a second end having a selected first surface feature formed thereon. When assembled, the first surface feature of the first housing part couples with the second surface feature of the second housing part to form a fluid connection therebetween.

According to one aspect, the first surface feature is sized and configured so as to only mate with the complementary shaped second surface feature to prevent another fluid delivering conduit having a differently configured surface feature from being

connected to the fluid receiving conduit, thereby preventing the accidental administration of another fluid to the patient through the first and second housing parts.

According to one practice, the medical connector of the invention can employ a set of first and second medical connector housing parts, each having a differently shaped surface feature. Each housing part can also be adapted for connection at one end to the fluid receiving conduit and has a differently shaped surface feature formed thereon. Additionally, the selected surface feature formed on the second housing parts have a complementary-shaped surface feature. The first and second medical connector housing parts when assembled couple multiple fluid delivering conduits to multiple fluid receiving conduits such that only a particular fluid receiving conduit is coupled to a particular fluid delivering conduit.

According to another aspect, each medical connector housing part further includes a fluid conduit formed therein. When assembled, the first and second fluid conduits allow passage of a fluid therethrough and from the fluid delivering conduit to the fluid receiving conduit.

According to still another aspect, the first and second housing parts form a non-universal medical connector that inhibits universal connectors from coupling the fluid delivering conduit to the fluid receiving conduit. The medical connector can further include a locking element formed on at least one of the first and second medical connector housing parts for securing the housing parts part together.

Brief Description of the Drawings

The foregoing and other objects, features and advantages of the invention will be apparent from the following description and apparent from the accompanying drawings, in which like reference characters refer to the same parts throughout the different views. The drawings illustrate principles of the invention and, although not to scale, show relative dimensions.

Figure 1 is a perspective view of one embodiment of a medical connector incorporating a selectively configured connection mechanism employing both raised and recessed surface features according to the teachings of the present invention.

Figure 2 is a perspective view of the medical connector of Figure 1 disposed in a closed or assembled position.

5 Figure 3 is an end view of the two half portion of a medical connector illustrating another embodiment of the connection mechanism in accordance with the teachings of the present invention.

10 Figure 4 is an unassembled perspective view of another embodiment of the medical connector in accordance with the teachings of the present invention.

Figures 5A through 5D illustrate various constructions of the connection mechanism in accordance with the teachings of the present invention.

15 Figures 6A through 6C illustrate various constructions of a locking mechanism suitable for use with the medical connector of the present invention.

Figures 7A through 7D illustrate the manner in which the medical connector of the present invention can be coupled to various fluid delivering or receiving devices.

20

Description of the Illustrated Embodiment

This present invention involves one or more, such as a family, of medical connectors with male and female halves which are shape- and/or size-indexed so that only complementary pairs of connectors may be coupled and then employed to deliver a fluid to a patient along a selected fluid pathway. The connectors of the present invention help avoid accidental administration of a fluid to the wrong fluid pathway by ensuring that fluid delivering devices can only be connected to a fluid receiving device having a specific configuration. The present invention may be adapted to many different medical applications in the field of medical connectors, injection apparatus, and infusion devices.

25
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Figure 1 shows a perspective view of two general medical connector portions, designated as a first male medical connector portion 1 and a second female medical connector portion 3, which incorporate in their first ends, respectively, a protuberance 15 and a cavity 25 complementary in shape to the protuberance. These surface features 5 allow the two connector halves to fit together in a fluid-tight seal, as shown in Figure 2. A fluid path runs through the long axis 4 of the first portion 1 and the second portion 2. Specifically, the medical connector portion 1 includes a central fluid lumen 10 that extends longitudinally therethrough from one end to the other. Likewise, the other medical connector portion 3 includes a central fluid lumen 60 that passes longitudinally 10 therethrough. When assembled, the fluid lumens 10, 60 are disposed in registration with one another to form an intermediate fluid pathway that connects a fluid delivering device to a fluid receiving device.

The illustrated first medical connector portion 1 has a surface feature formed on a mating end, such as the raised protuberance 15. The protuberance 15 can have many 15 shapes, and as illustrated is an annulus having an outer, flattened surface 5 that is disposed generally perpendicular to the long axis 4 of the connector 1 and the lumen 10. The second medical connector 3 has a complementary shaped surface feature, such as recess or cavity 25, which seats the protuberance 15 of the first connector portion 1. The recess 10 ends in a floor stop 65 which is designed to stop the advance of the 20 protuberance 15 when disposed within the recess. A central lumen 65 forms a second fluid pathway within the connector 3 and extends substantially from the recessed first end to the opposite end.

The matable complementary shaped surface features 15,25 of the medical connectors are designed to be incompatible with conventional type fittings, such as luer 25 taper fittings, which are a family of friction-fit, locking connectors of standardized size and shape, widely used in medical applications, and well known in the art. The surface features can have a variety of shape and sizes, such as illustrated in Figures 5A-5D.

The illustrated first medical connector 1 includes an outer housing having a recessed end which forms an outer annulus 26 that is coaxially disposed about the 30 protuberance 15. The outer annulus 26 includes a number of channels 28 formed therein, which terminate in a lock or key portion 29, formed towards an intermediate

portion of the medical connector. The medical connector 1 can further include a series of circumferential grooves 32 formed about the outer body portion of the connector. The grooves are preferably sized to seat a locking arm, Figure 6C, that can be formed on the other medical connector part for locking or securing the two connector components 5 together to form a fluid-tight seal.

With further reference to Figure 1, the medical connector portion 1 further includes a stepped outwardly extending housing portion 34, and a further outwardly extending portion 36 that extends along the longitudinal axis 4. This portion terminates in a flange or collar 55 adapted to connect with a fluid receiving or delivering device.

10 The other medical connector part 3 includes an outer housing portion 38 configured complementary to the mating end 20 of the other connector portion 1, so as to be able to couple thereto in a fluid sealing arrangement. Specifically, the outer housing portion 38 of the medical connector 3 terminates in a tab portion 35 that is designed to seat within the key portion 29 of the other medical connector portion 1. The connector 3 is further 15 tapered at an intermediate portion 42 and includes a cut-out portion 44. The connector terminates in a chamfered end 70 having an axially extending connector 50.

The two medical connector portions 1, 3 when mated together can either be held together by a friction fit arrangement, by the key locking scheme illustrated in Figure 1, or by a number of other locking schemes, as shown in Figures 6A through 6C. The 20 illustrated locking scheme involves seating the protuberance 15 in the recess 25 such that the mating portions of the two connectors are coaxially arranged. Furthermore, the outer housing 38 of connector 3 has an end 30 that seats within the space or channel 31 formed between the protuberance 15 and the outer annulus 26. Likewise, the outer end 20 of the protuberance is coaxially arranged with and seats about the outer surface or shell 38. In 25 order to assemble the connector parts, the portions 1 and 3 are pressed together, and the outer housing portions rotated around its long axis so that the tab 35 engages and locks with the complementary key portion 29. The assembled medical connector portions form a secure, fluid-tight medical connector 40 that couple together various fluid devices, such as catheters, needles, or syringes connected to the luer fittings 55 and 50, 30 as illustrated in Figure 2.

The illustrated medical connector portions 1, 3 of the invention are designed to be application or path-specific. The male or first connector portion 1 of the medical connector 40 is configured to mate with only one type of mating surface, although selected others are also contemplated, and will not mate with other female type 5 connectors. Thus a connector designated, for example, for epidural catheter injections is generally incapable of connection to a syringe intended for intravenous injection absent the specially configured surface feature. The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from distinctive markings on the outer surfaces of the half connectors. These 10 markings can include textured features, color coding and/or text labels, such as labels 70.

Each medical connector portion 1, 3 has an end 55, 50 opposite the mating surface or ends 20, 30 that are adapted to mate to a fluid delivering device, such as catheters, needles, syringes or other medical devices. In the illustrated connector of Figure 1, the ends 55, 50 can be standard luer taper fittings, either slip or locking type, 15 which are easily connected to the fluid delivering or receiving devices. Luer type fittings are well known and well characterized, and need not be described further herein. The use of safe and secure luer-type fluid fittings allow the safety medical connector 40 to be interposed between standard medical components now in widespread use. The medical connector 40 can also be permanently incorporated into various catheters, 20 connectors, syringes, tubing sets, and other devices designed for patient connection, as shown in Figures 7A-7D.

Figure 3 illustrates another type of connector design suitable for use in accordance with the present invention. The illustrated connector includes two connector portions 60, 62 designed to join together to form a fluid-tight seal for the injection or infusion of a medication or medical fluid, or alternatively for the evacuation of a body 25 fluid, via a catheter or device placed into the patient's vein, artery, epidural or spinal space, or other body compartment. The medical connector portions 60 includes a quadrilateral shaped raised surface feature 66 extending from one end 60A. The connector includes a fluid lumen 68 formed therein that extends between the connector 30 ends. The other connector portion 62 has a recessed surface feature 72 complementary in shape to the raised feature in order to accommodate and properly seat the raised

feature to form a fluid tight seal. According to one practice, the end region 62A includes a cavity 72 that has a floor portion 74. The floor portion is apertured with an opening that defines the fluid lumen 70. The lumen extends between the connector ends.

When assembled, the protuberance 66 seats within the cavity 72 to dispose the

5 lumen 68 in fluid communication with the lumen 70 to form a continuous fluid path along the assembled connector and between, for example, an infusion or injection source and a patient catheter. The two connector portions 60, 62 can be locked together using a variety of different schemes as discussed below. The locked pair of medical connector portions can include additional connection sites (such as luer fittings) on the ends

10 opposite the mating surfaces 60A, 62A which allow the device to be inserted between the patient and the injection, infusion, or evacuation source. For example, the basic design can consist of standard luer taper fittings attached to each medical connector half. Therefore, an epidural catheter 80 can be connected via its female luer hub adapter 82 to a male luer fitting 84 coupled to one end of a medical connector, generally illustrated as

15 medical connector portion 86, configured in accordance with the present invention. The connector 86 couples to the other connector half to complete the medical connection. According to one practice, the illustrated connector 86, when not coupled to its mating connector, generally cannot be connected to any standard syringe or medical tubing which is devoid of a complementary surface feature.

20 Figures 5A through 5D illustrate still other embodiments of the surface features which can be formed on the mating ends of the medical connectors in accordance with the present invention. In each case, a complementary pair of protuberances and recesses are incorporated into the medical connectors. In Figure 5A, the protuberances can have a variety of geometric shapes, which are arranged coaxially around the lumen 10. The

25 shapes of the surface features can further include a triangle 100, square 105, pentagon 110, hexagon 115, or other regular polygon or quadrilateral shape. As is readily apparent to those of ordinary skill, each illustrated surface feature can replace the cylindrical protuberance 15 of Figure 1. The raised surface features fit into a complementary shaped and sized cavity formed in the other medical connector half.

Figures 5B and 5C illustrate employing raised surface features that have varying sizes. In these instances, the lumen 10 is surrounded by a cylindrical protuberance of small 130, intermediate 135, or larger 140 diameter, or alternatively a regular polygon of small 145, intermediate 150, or larger 155 size. Figure 5D illustrates employing radial 5 projections in an outer surface of the connector half, to effectuate radial pin indexing. In this configuration, radially spaced pins 160 are arranged circumferentially about the protuberance 15. These pins uniquely mate with complementary slots 165 arranged radially within the walls of the cavity 25 formed in the other connector half.

The foregoing medical connectors can be fashioned from hard plastic or other 10 suitably minimally deformable material, so that incompatible connector halves cannot mate in a fluid-tight manner. Attempts to do so will cause the fluid path to leak, preventing inadvertent injection. Integrity of the fluid path can be ensured either by a tight friction fit between the complementary connector parts, or by the inclusion of an integral rubber or other deformable gasket on the male portion of the connector pair. 15 This gasket would be slightly larger in its non-deformed state than the complementary female half connector's cavity, so that when the two connectors are mated, the gasket deforms and causes a tight seal.

Two complementary medical connector portions can be joined together to form a complete medical connector. Once assembled, the connector portions can be locked into 20 the mated or joined position in a variety of ways. Some examples of locking arrangements suitable for use with the medical connector of the present invention are illustrated in Figures 1 and 6A through 6C. As described above, the connector portions 1 and 3 of Figure 1 include a key and tab engagement arrangement to secure the connector halves together. Figure 6A illustrates a pair of medical connectors 200 and 25 205 which can be assembled and held together with a simple friction fit. In this configuration, the mating portion of connector 200 is slightly smaller in size than the complementary connector 205 so that when engaged, sufficient force is required to separate the connector pair such that ordinary injection pressures do not separate them. Specifically, the medical connectors 200, 205 require some amount of force to separate 30 the connector portions. The tolerances of the two mating medical connector portions are

such that the pressure in the fluid delivering or receiving conduits attached to the connector are generally insufficient to drive the pair apart.

Figure 6B illustrates another of securing or locking the connectors 300 and 320 together. In this embodiment, the connector 305 includes a stepped axially extending lip portion 305 formed on the mating end of the connector. The lip of the larger connector includes a slightly raised portion or detent 306 extending radially inwardly towards or into the lumen. The lip 305 is adapted for engagement with a complementary channel or indent formed in the mating end of the other connector 320, which is of slightly smaller diameter. The two connector halves can lock together with a pushing action, with one side designed to pass over the other. When assembled, the smaller connector 320 is pushed within the larger connector half 300 until the lip 305 engages the complementary indent 310, thereby securing the connector portions together.

Figure 6C shows the similar arrangement of two outer housings of slightly different diameters 300 and 320 with slots 400 formed on the outer surface of connector 320, which engage slightly spreadable or deformable fingers 405 attached to and extending from the other connector half.

Still other embodiments of securing mechanisms include providing connector portions that contain a central fluid lumen, and ending in luer or other fittings for connection to medical tubing, syringes, or catheters. The entire inner portion of the connector is adapted to spin freely around the axis of the fluid lumen. When assembling together the two medical connector halves, the inner portions of the connectors mate together, and then the outer housing portions of the connectors are twisted together to lock them. Several mechanisms for locking the outer portions are possible. The two outer housings could be designed with complementary deformable tabs and slots which engage when twisted together, threaded ends which screw together, or fingers on one part which lock into slots on the other part, as described above in connection with Figures 6A through 6C. Another embodiment of a securing mechanism can include configuring the inner mating portions of the connector portions so as not to spin along the axis of the fluid lumen.

As described above, the foregoing medical connectors function as a basic interface between standard fluid delivering and receiving devices, such as standard catheters and infection sources, via standard medical luer fittings. In the usual application, one connector portion of the present invention contains at its non-mating 5 end a male luer fitting with or without a standard twist-lock feature, and the other connector contains a similarly positioned female luer fitting. In certain specialized applications, twin female or male luer adapters could be incorporated.

This medical connectors of the invention can also be fitted with connectors at the non-mating ends that allow its connection to other medical devices and containers. In 10 one important embodiment of this invention, one connector half is permanently fused to or incorporated into a standard medical infusion device, so that use of a complementary connector is mandatory to access the catheter or device. For example, an epidural catheter adapter, which typically grips a 18 to 21 G epidural catheter and ends in a female luer fitting, is mounted to one end of the medical connector half. Only a syringe 15 or tubing set incorporating or fitted with the complementary half connector can be used with this type of epidural catheter. Any catheter, injection adapter, tubing set, syringe, or device connecting to a patient catheter and currently using luer universal connectors can be adapted to incorporate half connectors of a given type from the present invention. The invention thus allows a family of safety injection sources and catheters to replace 20 the inherently less safe universal connectors in wide use today.

The foregoing safety medical connectors are designed to be interposed between existing devices for medical infusions, injections, or aspirations. An additional feature of the present invention is the fusion of a half connector as illustrated in Figure 1 into a standard medical connector or device. Figures 7A through 7D illustrate the 25 incorporation of a safety connector half into an epidural catheter connector 500, which in turn is connected to an epidural catheter 505. Any of the mating and locking configurations of the present invention, for example the rectangular surface feature 510, can be incorporated into the end of the epidural catheter connector. The epidural catheter connector in turn mates with a complementary safety connector half 520. This 30 connector half includes a complementary shaped surface feature that ensures that only

medications intended for epidural delivery are injected through the epidural catheter, since only a specific surface feature 510 can mate with the connector half 520.

Figure 7B illustrates another example of attachment mechanisms adapted for use with the medical connector of the present invention. The illustrated medical connector 5 can be coupled to a hollow sharpened spike designed for piercing bags of intravenous fluids, blood products, or premixed intravenous medications; a connector to feeding tubes; or a connector for certain specialized catheters used in peritoneal dialysis. Specifically, a half connector 1 is incorporated into a tubing set for infusion of fluids or medications into a patient, typically comprised of tubing 540 and a spike 535 for 10 piercing a container of fluid or medication, which can be seen to be infusing through a transparent drip chamber 530. In still another configuration, as shown in figure 7C, a half connector 1 is incorporated into a syringe 545. In another embodiment, as shown in Figure 7D, a half connector 1 is incorporated into a three-way stopcock 550 which allows entry of medication or withdrawal of fluids or medications from a tubing set 555.

15 Other variations of the basic design of the medical connector of the present invention are contemplated by this invention and thus form part of the description. First, one medical connector half may be fused permanently or incorporated into an existing medical infusion or injection device. For example, a syringe prefilled with a medication that can only be given safely by a certain route could be fashioned with a half connector 20 on its end. Only by mating with a catheter fitted with the appropriate complementary connector part (perhaps also permanently mounted) can the injection be given. Tubing sets designed for particular applications such as epidural anesthetic infusions can be fashioned with injection sites which only connect to other complementary connector parts. Thus, while allowing simple and needleless injection of additional medications, 25 inadvertent injection of inappropriate medications would be significantly less likely, and hence prevented.

In other designs, either or both medical connector portions can be fitted with a valve which is disposed in a normally closed position but is opened by appropriate mating with a complementary connector. A spring loaded mechanism closes the valve 30 whenever the connector parts are disconnected, preventing fluid leaks and contamination of the lumen. The connector portions can also be configured to connect to standard

medical infusion devices or catheters via essentially irreversible mechanisms so that, once connected, the safety of the device cannot be subverted by removing one half connector to restore a universal connection. An example of such an application is the preservation of one lumen of a central venous catheter exclusively for infusion of

5 parenteral nutrition solutions. Commonly, warning labels or adhesive tape are placed over the rubber septum cap on the end of such a port, but these are easily subverted. A locked half connector from the present invention would all but eliminate this problem. Two such methods for locking the connectors are as follows. First, a modified screw-type male luer adapter with a wedge shaped enlargement incorporated into the screw

10 threads may be substituted for an ordinary male luer adapter. A tab on the circumferential edge of a standard female luer adapter normally engages the threads in the male screw-type luer connector. When it meets the wedge in the threads of the modified adapter described here, it follows the ramped edge of the wedge, slightly deforming the threaded connector until it crosses the end of the wedge and returns to the

15 threaded path. Because the wedge is placed so that the narrow end is contacted first during clockwise (tightening) rotation of the male luer adapter, unscrewing of the adapter once the wedge has been passed will be very difficult or impossible.

A second method for locking the present invention to an existing female luer adapter is to dispose a coaxial collar about the adapter. The inner male screw adapter is

20 of standard design, and an outer collar is adapted to spin about its long axis (which includes the fluid path). Teeth arranged in the space between the male luer screw portion and the outer collar allow the outer collar to turn the inner male luer screw fitting only in the clockwise direction. Counterclockwise rotation is impossible because the teeth do not engage, and therefore once the modified male luer adapter has been screwed

25 onto the female luer adapter, unscrewing them is difficult or impossible.

Still another modification of the connector of the invention is a family of accessory caps for covering the unmated half connectors of the basic device or its modifications as described elsewhere in this section. These caps have inner surfaces complementary to the male or female connector halves and insert over the mating

30 surface of the connector half, preferably with a friction-fit.

This invention is designed to be used in both routine and emergency medical care. As such, simple and rapid identification of the complementary half connectors is important. Besides inspection of the mating surfaces themselves, a variety of techniques may be utilized to ease identification of the connectors (see Section 5). The preferred 5 implementation of this technology into medical practice would involve standardization of the various connector types to be used only for certain catheters. For example, there could be one type only used for epidural catheters, one for peripheral intravenous catheters, and another for central venous catheters.

In certain applications, the medical connectors of the present invention may be 10 advantageously employed with indwelling lines, i.e., central and peripheral intravenous lines, to offer selectivity relative to the fluid delivering device. For example, a syringe filled with a medicament that can be safely administered both peripherally and centrally, such as morphine, should be able to mate, via the medical connectors of the present invention, with the central and peripheral intravenous lines. In this embodiment, a pair 15 of first housing parts having the same surface feature are coupled to both fluid receiving or indwelling pathways. The syringe (fluid delivering device) has coupled thereto a connector half that has a shape complementary to the shape of the other surface feature, thus enabling this connector and syringe to couple to both fluid pathways, and nothing else, if desired. However, a medicament that is not safely administered peripherally, 20 such as potassium chloride, can be pre-filled in a syringe that could mate only with the connector half associated with the central line. Hence, the central intravenous line or pathway mates with both the central and peripheral compatible syringes, but the peripheral line connector only mates with the peripheral syringe. The central and peripheral lines can be manufactured with such fittings as integral parts, or as 25 irreversibly attachable connectors when site specificity is warranted.

The general concept embodied in this technology, in summary, is that medical connectors are made path-specific rather than universal. This general description is of a pair of connectors disposed between standard fluid delivering and receiving devices.

It will thus be seen that the invention efficiently attains the objects set forth 30 above, among those made apparent from the preceding description. Since certain changes may be made in the above constructions without departing from the scope of

the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are to cover all generic
5 and specific features of the invention described herein, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described the invention, what is claimed as new and desired to be secured by Letters Patent is:

Claims

1. A medical connector suitable for use in coupling a fluid delivering conduit to a fluid receiving conduit, such as a catheter adapted for insertion within a patient, said medical connector comprising
 - a first medical connector housing part having a first end sized to mate with the fluid receiving conduit and a second end having a selected first surface feature formed thereon, and
 - a second medical connector housing part having a first end configured to mate with the fluid delivering conduit and a second end having a selected second surface feature complementary in shape to the first surface feature of the first housing part, so that when assembled the first surface feature of the first housing part couples with the second surface feature of the second housing part to form a fluid connection therebetween,
- 10 wherein said first surface feature is sized and configured so as to only mate with the complementary shaped second surface feature to prevent another fluid delivering conduit having a differently configured surface feature from being connected to the fluid receiving conduit, thereby preventing the accidental administration of another fluid to the patient through the first and second housing parts.
- 15
- 20
2. The medical connector of claim 1, wherein said first medical connector housing part further includes means forming a first fluid conduit therein, and said second medical connector housing part includes forming a second fluid conduit therein, wherein when said housing parts are assembled, the first and second fluid conduits allow passage of a fluid therethrough and from the fluid delivering conduit to the fluid receiving conduit.
- 25

3. The medical connector of claim 1, further comprising
a set of first medical connector housing parts, each housing part being adapted
for connection at one end to the fluid receiving conduit and having a selected surface
feature formed on the other end, each first housing part having a differently shaped
5 surface feature, and
a set of second medical connector housing parts, each housing part being adapted
for connection at one end to the fluid delivering conduit and having a selected surface
feature formed on the other end, each second housing part having a differently shaped
surface feature, each of which is complementary in shape to one of said first surface
10 features,
wherein said first and second medical connector housing parts when assembled
couple multiple fluid delivering conduits to multiple fluid receiving conduits such that
only a particular fluid receiving conduit is coupled to a particular fluid delivering
conduit.
15
4. The medical connector of claim 1, wherein said first surface feature is a
protrusion and said second surface feature is a recess.
5. The medical connector of claim 1, wherein said first and second housing parts
20 when assembled form a non-universal medical connector that inhibits universal
connectors from coupling the fluid delivering conduit to the fluid receiving conduit.
6. The medical connector of claim 1, wherein said medical connector further
comprises a locking element formed on at least one of said first and second medical
25 connector housing parts for securing said first connector housing part to said second
medical connector housing part.

7. A method of delivering a fluid from a fluid delivering conduit to patient from a fluid receiving conduit through a selected fluid pathway, said method comprising step of providing a first medical connector housing part having a first end sized to mate with the fluid receiving conduit and a second end having a selected first surface feature formed thereon, and

providing a second medical connector housing part having a first end configured to mate with the fluid delivering conduit and a second end having a selected second surface feature complementary in shape to the first surface feature of the first housing part, so that when assembled the first surface feature of the first housing part couples with the second surface feature of the second housing part to form a fluid connection therebetween,

wherein said first surface feature is sized and configured so as to only mate with the complementary shaped second surface feature to prevent another fluid delivering conduit having a differently configured surface feature from being connected to the fluid receiving conduit, thereby preventing the accidental administration of another fluid to the patient through the first and second housing parts.

8. The method of claim 7, further comprising the step of forming a first fluid conduit within said first medical connector part and a second fluid conduit within said second medical connector part.

9. The method of claim 8, further comprising assembling said housing parts such that the first and second fluid conduits allow passage of a fluid therethrough and from the fluid delivering conduit to the fluid receiving conduit.

10. The method of claim 7, further comprising the steps of
providing a set of first medical connector housing parts, each housing part being
adapted for connection at one end to the fluid receiving conduit and having a selected
surface feature formed on the other end, each first housing part having a differently
shaped surface feature, and
5 providing a set of second medical connector housing parts, each housing part
being adapted for connection at one end to the fluid delivering conduit and having a
selected surface feature formed on the other end, each second housing part having a
differently shaped surface feature, each of which is complementary in shape to one of
10 said first surface features,
wherein said first and second medical connector housing parts when assembled
couple multiple fluid delivering conduits to multiple fluid receiving conduits such that
only a particular fluid receiving conduit is coupled to a particular fluid delivering
conduit.
15
11. The method of claim 7, further comprising the step of forming a non-universal
medical connector that inhibits universal connectors from coupling the fluid delivering
conduit to the fluid receiving conduit from said first and second medical connector parts.
20 12. The method of claim 7, further comprising the step of providing a locking
element on at least one of said first and second medical connector housing parts for
securing said first medical connector housing part to said second medical connector
housing part.

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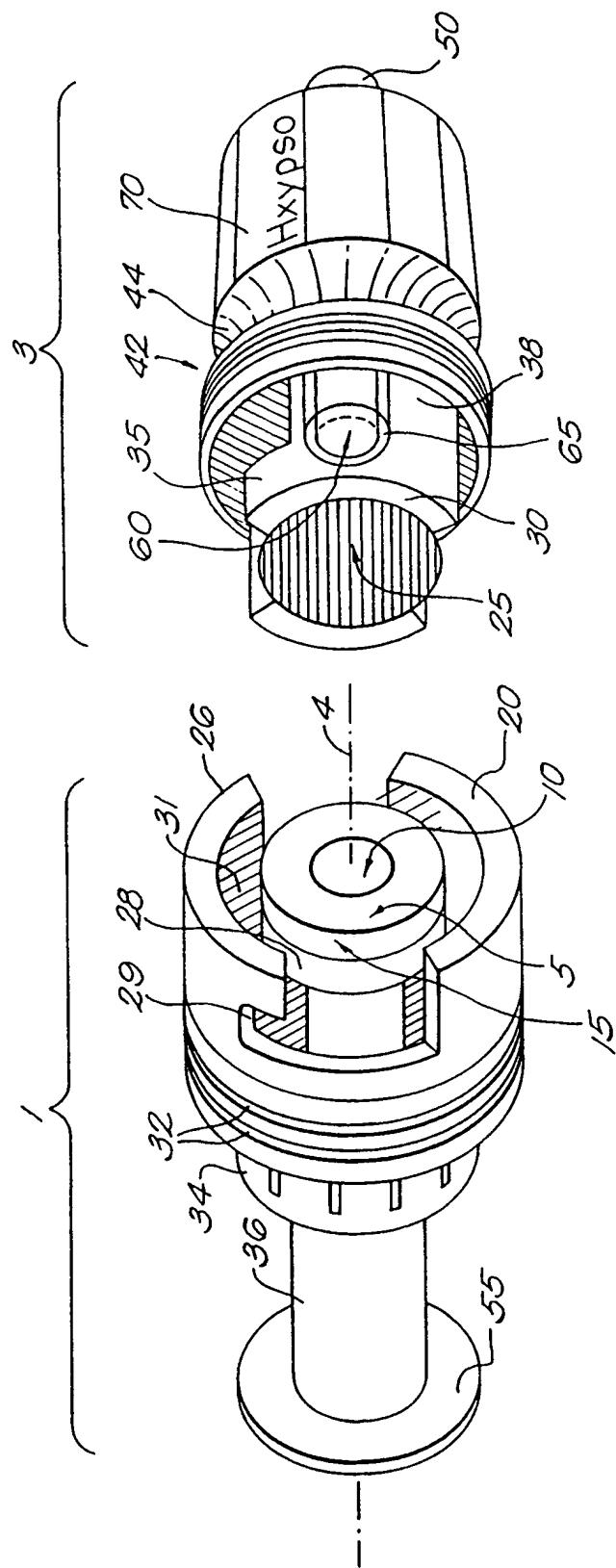


FIG. I

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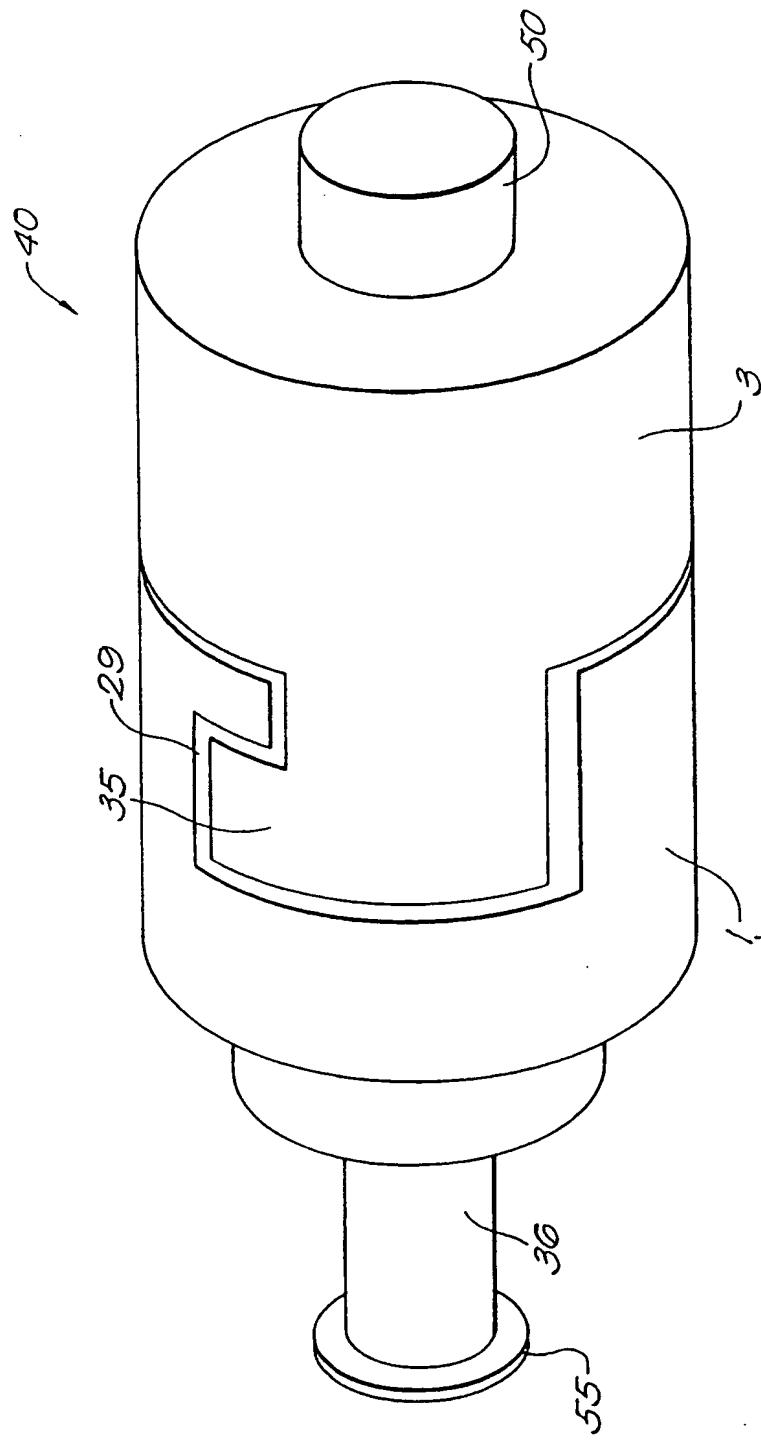


FIG. 2

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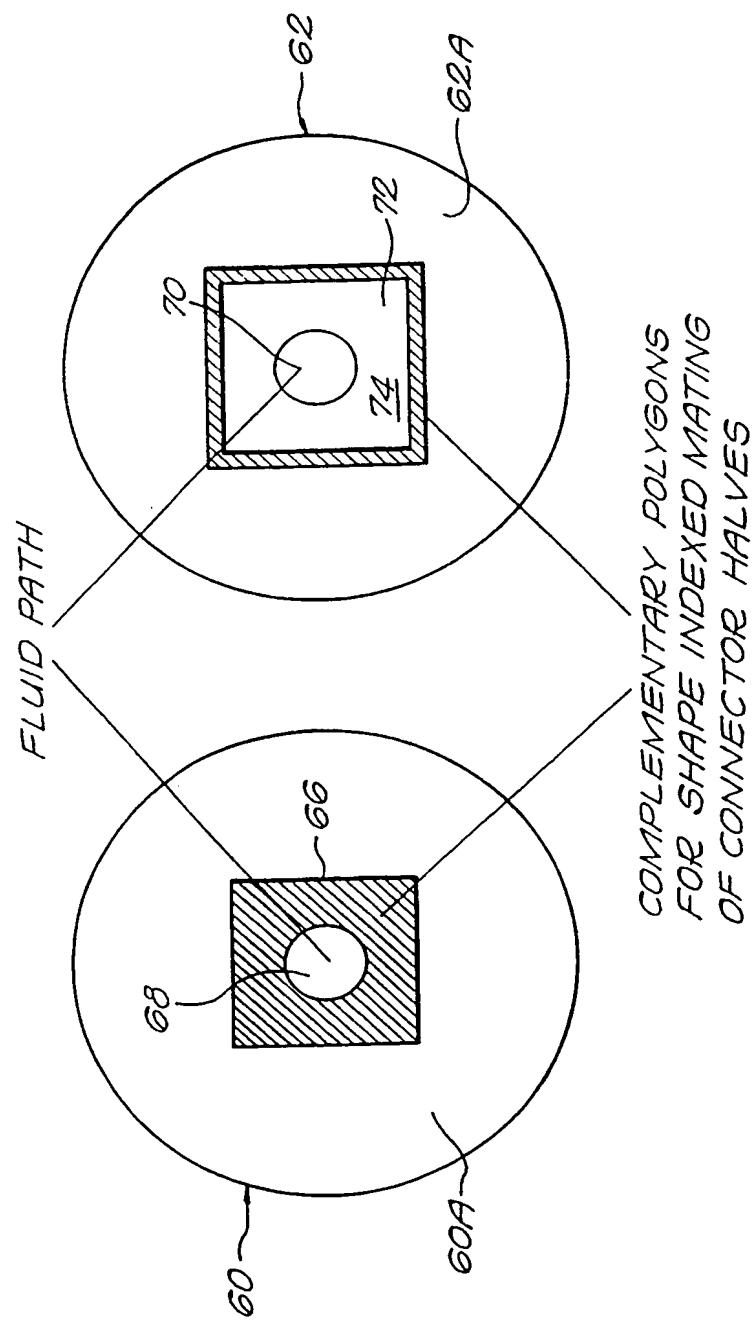


FIG. 3

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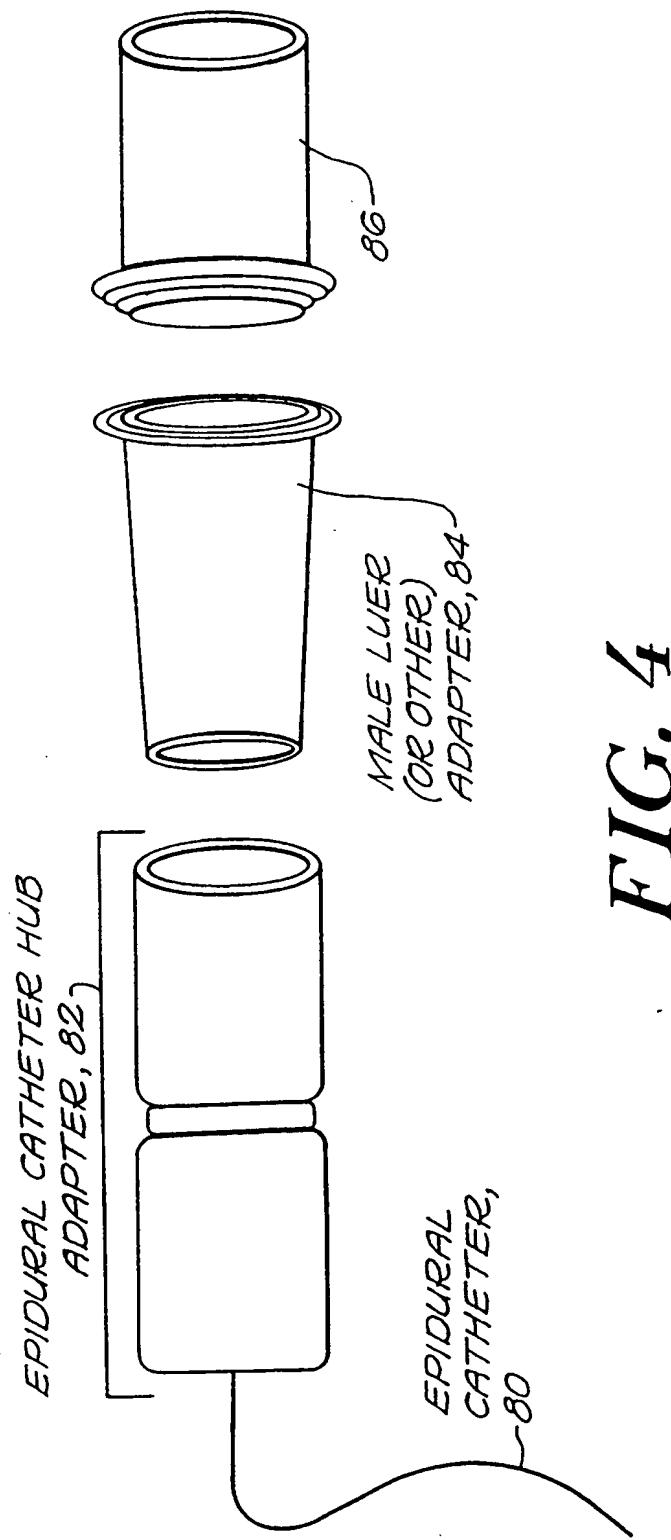


FIG. 4

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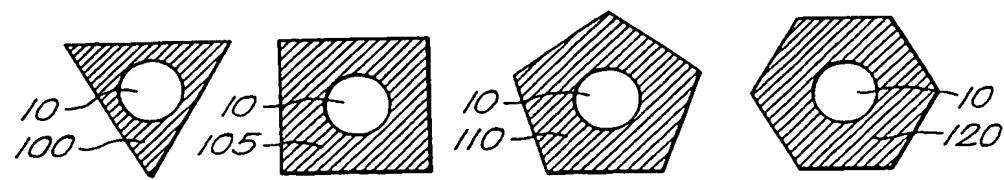


FIG. 5A

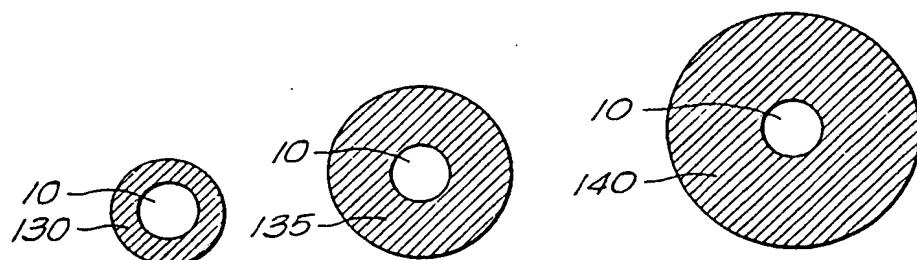


FIG. 5B

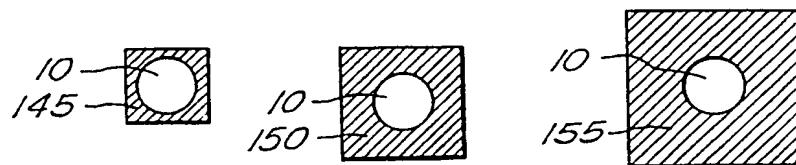


FIG. 5C

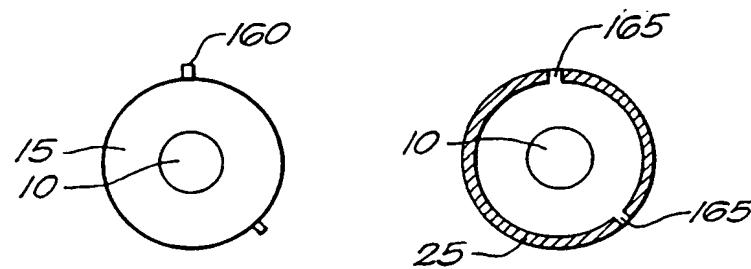


FIG. 5D

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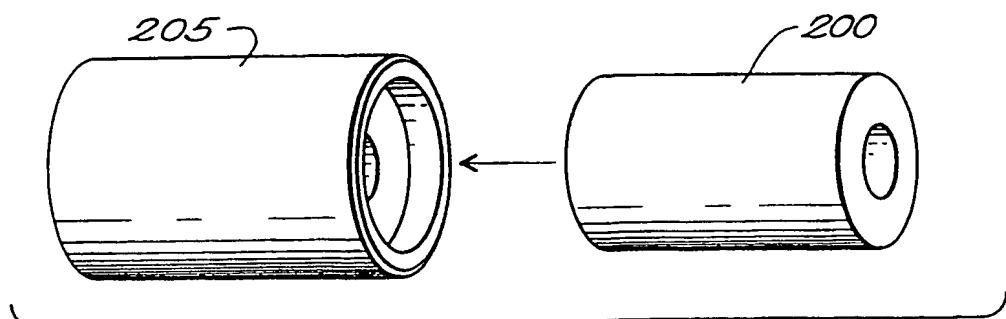


FIG. 6A

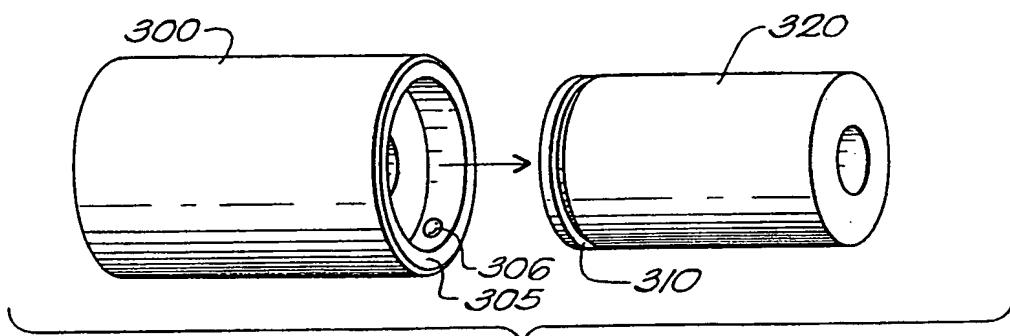


FIG. 6B

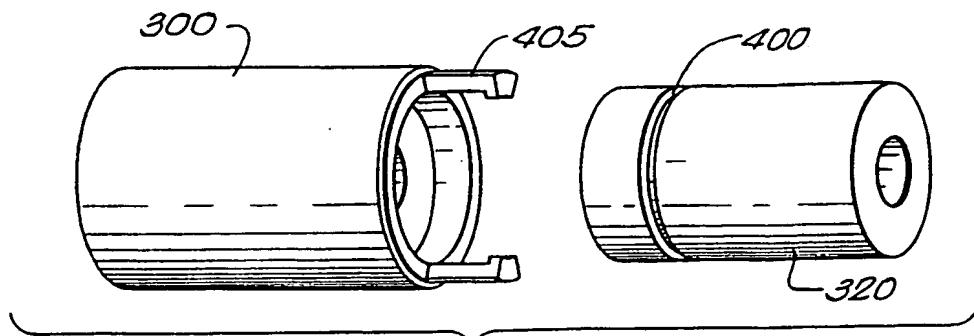


FIG. 6C

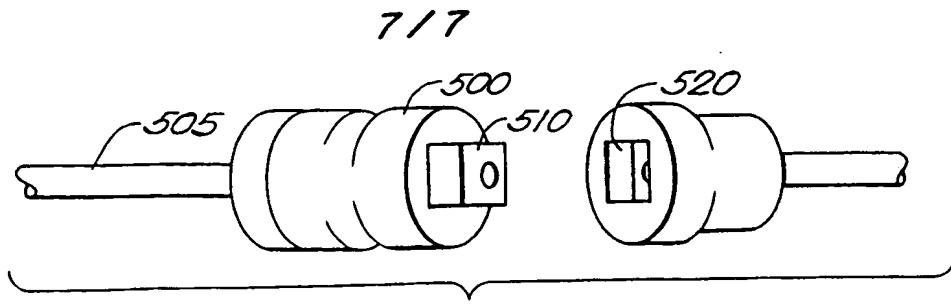


FIG. 7A

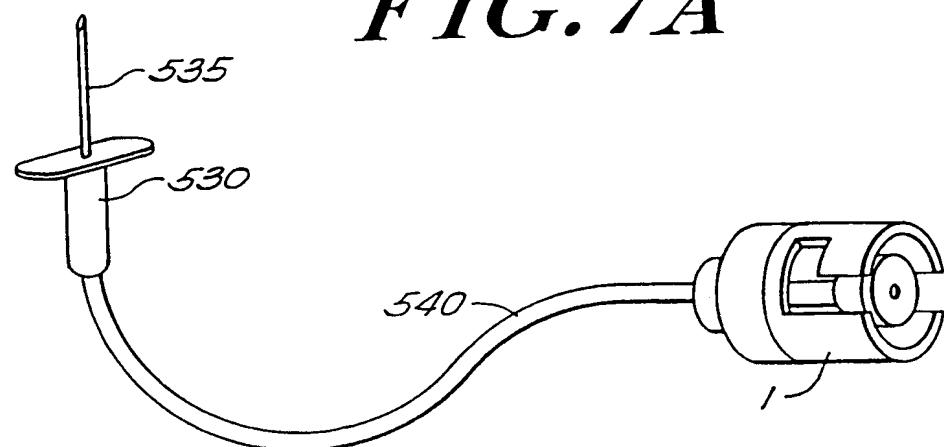


FIG. 7B

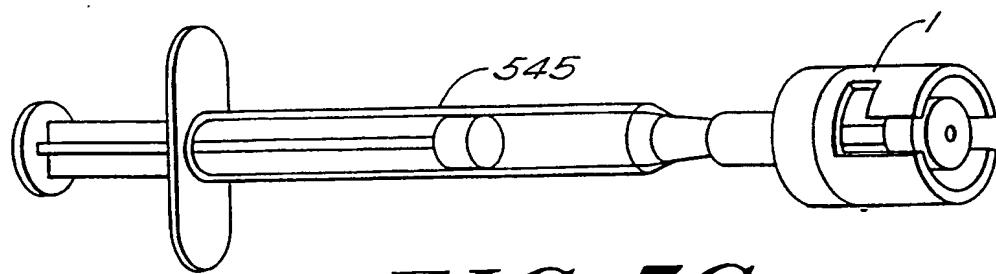


FIG. 7C

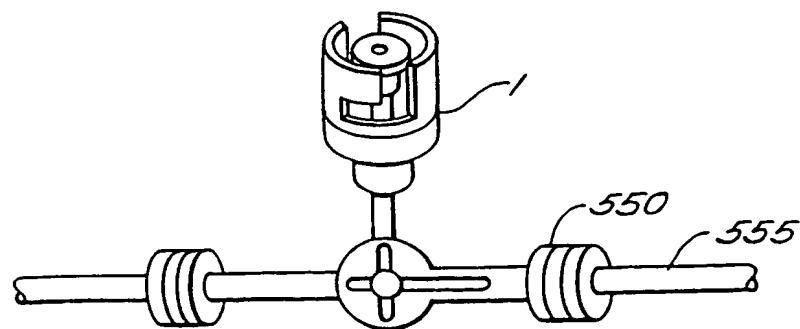


FIG. 7D

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12878

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M39/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 619 640 A (POTOLSKY ET AL.) 28 October 1986 (1986-10-28) column 2, line 65 -column 5, line 65 figures 2-5 ---	1,2,4-6
X	EP 0 774 270 A (DELVIGO) 21 May 1997 (1997-05-21) column 2, line 25 - line 55 column 3, line 39 -column 4, line 44 figures 2,3 ---	1,2,4-6
X	US 4 150 673 A (WATT) 24 April 1979 (1979-04-24) column 2, line 65 -column 3, line 25 figures 1-3 ---	1-3 -/-



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

30 September 1999

Date of mailing of the international search report

07/10/1999

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12878

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 217 055 A (KAWASUNI LABORATORIES, INC.) 8 April 1987 (1987-04-08) page 8, line 4 -page 9, line 1 figures 1-3,15 -----	1,2,4-6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 12878

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 7-12 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/12878

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